A Survey of Postdural Puncture Headache Management Practices within an Academic Department

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in the partial fulfilment of the requirements for the degree of

Master of Medicine in the branch of Anaesthesiology

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Declaration

I, Kathryn Monteith, herewith declare that this research report is my own, unaided work. It is being submitted for the degree of Master of Medicine at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

Signed

On this 21st day of March 2022

Dedication

Thank you to my family for all their patience and support during the MMED process.

Abstract

Background

Postdural puncture headache (PDPH) is a common consequence of neuraxial anaesthesia, especially among parturients, in whom it is associated with maternal morbidity, prolonged hospital stay, and increased healthcare costs. Although international guidelines for PDPH management are available, variable management practices exist. There are no published studies which document current practices, nor guidelines available, with respect to PDPH management in South Africa. This study aims to describe PDPH management practices within the Wits Department of Anaesthesiology, which may assist in future local guideline or protocol development.

Methods

An electronic questionnaire was distributed to the Wits Department of Anaesthesiology. The survey instrument was developed following a literature review targeting recent evidence based PDPH management guidelines, including the Obstetric Anaesthetists Association (OAA) guidelines from 2018, after which it was reviewed for content and face validity. Data were downloaded, analysed, and presented with the aid of statistical software. Participant responses were then compared to the OAA guidelines, which were considered the standard of practice. A score relating to this was determined and compared to demographic variables to assess for possible correlations.

Results

Participants' practice with respect to conservative management strategies and the performance of EDBPs was in keeping with the OAA guidelines, despite evidence of limited provider experience with performing these procedures, as well as the lack of available departmental guidelines. Ninety six percent of anaesthetists perceived they would benefit from the institution of formal guidelines.

Conclusions

Management practices for the treatment of PDPH among anaesthetists within the Wits circuit are variable, but generally consistent with current international guidelines, however, limited experience in treating PDPH has been demonstrated.

The development, and institution, of formal guidelines to assist in the management of PDPH is recommended, as well as continuous medical education of staff, to ensure good patient outcomes. (Word Count:293)

Acknowledgements

A thank you to my supervisors, Janine Wagner and Julie-Ann Herbst for all their insight, guidance and support.

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List of Abbreviations

PDPH	Postdural puncture headache
Wits	University of the Witwatersrand
ADP	Accidental Dural Puncture
EDBP	Epidural blood patch
OAA	Obstetric Anaesthetists' Association
SPGB	Sphenopalatine ganglion block
IV	Intravenous
FBC	Full blood count
U & E	Urea and Electrolytes
CRP	C-Reactive Protein
CT Scan	Computed Tomography Scan
MRI	Magnetic resonance imaging
SAPPG	South Australian Perinatal Practice Guidelines
NSAIDs	Non-steroidal anti-inflammatory drugs
UK	United Kingdom

Statement

The Research Report consists of a literature review, draft article, study proposal and appendices. The literature review and study proposal are included for background reference and are not intended for examination.

The formatting of this Research Report, but not the draft article, complies with the University of the Witwatersrand's Style Guide for Theses, Dissertations and Research Reports.

The formatting of the draft article is in keeping with the author guidelines (Section 2 page 24) stipulated by the South African Journal of Anaesthesia and Analgesia, the journal to which it is intended to be submitted.

Section 1: Review of the Literature

1.1 Introduction

The purpose of this literature review is to discuss PDPH and its management. An introduction to PDPH, its pathophysiology, incidence, differentials, and consequences will be discussed, thereafter the present international management guidelines will be explored, and actual practice internationally and locally will be reviewed. Finally, the importance of guidelines in the management of PDPH will be established.

1.2 Definition

A postdural puncture headache (PDPH) is defined by the International Headache Society as a "headache occurring within five days of a lumbar puncture, which is caused by cerebrospinal fluid (CSF) leakage through the dural puncture. It is usually accompanied by neck stiffness and/or subjective hearing symptoms. It remits spontaneously within two weeks, or after sealing of the leak with autologous epidural lumbar patch" (1). It is typically worse on movement, especially from the supine to upright position (2). It results from any procedure which may cause a dural puncture, either intentional or unintentional, including spinal and epidural anaesthesia (2).

1.3 Pathophysiology

The pathophysiology of PDPH remains unclear, but it is thought to be caused by a CSF leak where the rate of leakage exceeds that of production, resulting in intracranial hypotension and traction on the meninges, which causes parasympathetic vasodilation of the meningeal blood vessels and the resultant headache (2, 3).The postural worsening of the headache is thought to be due to the worsened 'sagging' of intracranial structures that is noted in an upright position (4, 5).

1.4 Risk factors and international incidence

PDPH is a common consequence of spinal and epidural anaesthesia, with an incidence of approximately 1% (6-8). Non-modifiable risk factors for PDPH include age (with 20-30 year-olds bearing the highest risk), female gender, previous PDPH, low body mass index, and a history of chronic headaches (2). Modifiable risk factors include spinal needle size and shape, as well as operator experience and some factors related to technique (2). The incidence of PDPH is greatly influenced by the size and type of needle used. Smaller pencil point needles are associated with a lower incidence of PDPH compared to larger or cutting needles (6, 9). The various types of spinal needles are demonstrated in Figure 1 below. There is a 0.5–2% incidence of PDPH after spinal anaesthesia using small pencil point needles (6, 10). There is a much higher incidence of PDPH after accidental dural puncture (ADP) during the performance of an epidural, with approximate rates of 45-80%, but as high as 88% with the use of a 16G Tuohy needle (6, 10, 11). The rate of ADP has been reported at 0.5-4% (7, 10).

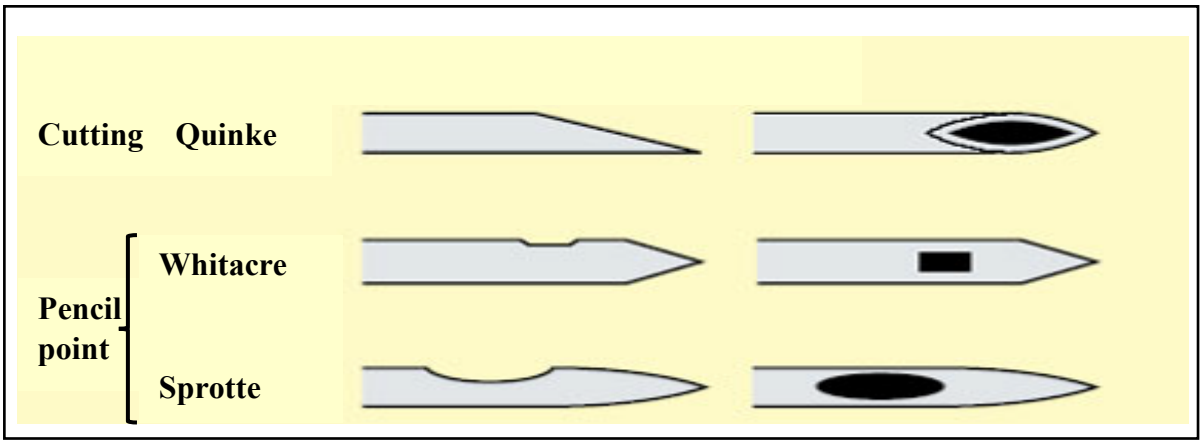


Figure 1: Spinal needle designs (12)

1.5 The incidence of PDPH in South Africa

Literature available from South African academic hospitals suggests that the rate of PDPH may be up to two to three times higher than that in high income countries. A study by Jacobs-Martin et al. (13) demonstrated a 3.4% incidence of PDPH after epidural anaesthesia at Tygerberg Academic Hospital in 2012.

A follow up on this study, by van Zyl et al. (14), demonstrated that the rate of PDPH at Tygerberg Academic Hospital was 0.7% and 0.4% in 2014 and 2015 respectively. These results are more in keeping with international estimates. The higher PDPH headache incidence reported by Jacobs-Martin et al. (13) may be related to poor skill development as a result of low epidural rates. Epidural rates in South African academic hospitals have been reported to be as low as 2.2%, whereas rates in other high-income countries, such as the United Kingdom and United States, have been reported as 31% and 61% respectively (13, 15, 16). ADP rate has been reported between 2.6% and 4.1% in South African studies (13, 14).

1.6 Consequences of PDPH

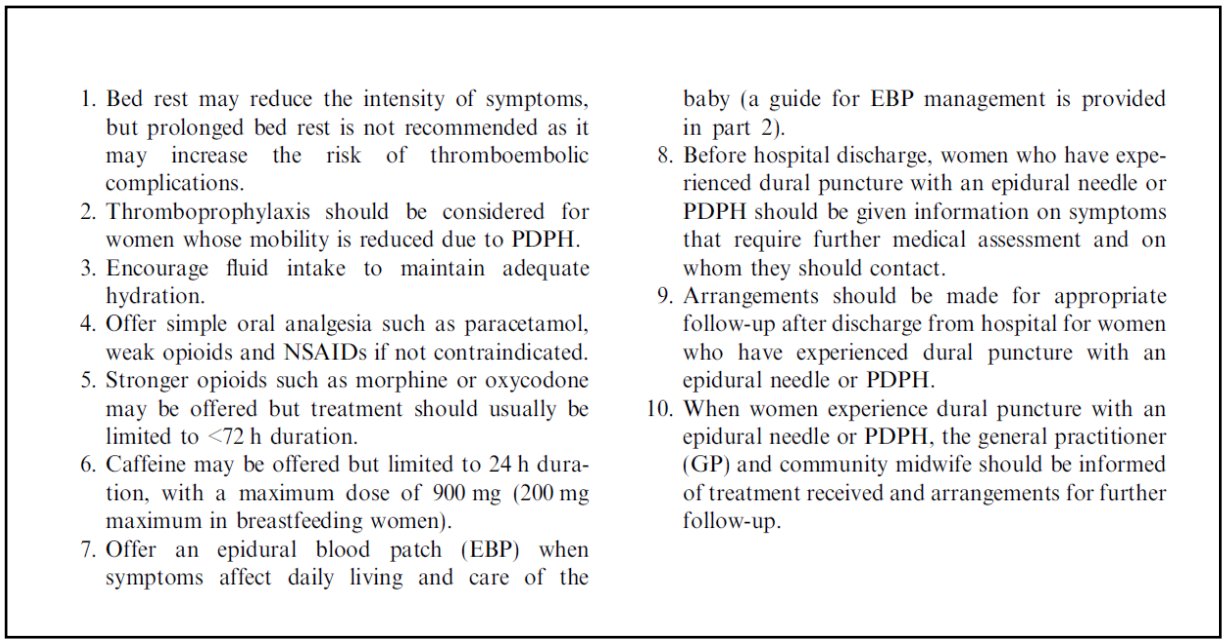
PDPH can be debilitating and result in poor maternal-baby interaction, difficulty breastfeeding, decreased mobility, increased duration of hospital-stay, recurrent hospital admissions, and increased hospital costs (7, 17). PDPH has been associated with chronic headaches, increased incidence of postpartum depression and post-traumatic stress disorder, as well as more serious morbidity such as cranial nerve palsies, venous sinus thrombosis, and subdural haemorrhage (4, 7, 8, 17). Subdural haemorrhage, in particular, has been linked with PDPH in many case reports and is thought to result from tearing of the intracerebral bridging veins secondary to significant intracranial hypotension (18). This may result in maternal mortality (19, 20). Poorly managed PDPH may also result in poor patient satisfaction, increased rates of litigation, and associated legal costs (21, 22).

1.7 Differential diagnosis

It is essential to consider the differential diagnoses of PDPH both before diagnosis and during management, especially if the headache is atypical, not improving with recommended therapy, or changes in nature (4). Some of these differentials include other causes of primary headaches, such as tension headaches or migraines, headaches related to hypertension or pre-eclampsia in pregnancy, or vascular causes including ischaemic, thrombotic and haemorrhagic (2, 4, 23). Alternative diagnoses include sinusitis, meningitis, intracranial mass lesions, pneumocephalus, caffeine withdrawal, and drug related causes (2, 23).

1.8 International management recommendations

There is little consensus with regards to the best approach to managing PDPH, and much of the existing advice on the management of PDPH is "based on very little robust scientific evidence" or is of a lower evidence level (4). The most recent guidelines, at the time this paper was written, include the Obstetric Anaesthetists' Association (OAA) PDPH Guidelines from December 2018 (Figure 2) and the South Australian Perinatal Practice Guidelines (SAPPG) from November 2017 and both guidelines focus on management of PDPH in the obstetric population (Figure 3) (4, 5, 23, 24). Both guidelines are based on a review of the literature and expert opinion. The guidelines discuss some of the modalities of treatment, including conservative and pharmacological management, invasive procedures, epidural fluid administration, epidural blood patches and miscellaneous treatments including nerve blocks (4, 23, 24). The OAA guidelines appear to be more detailed and comprehensive, with 231 references cited in the full edition, compared to the SAPPG ones, which cite only 15 references. As a result, the OAA guidelines have been used as the standard of care for PDPH management in this paper (4, 5, 23, 24).



1. Bed rest may reduce the intensity of symptoms, but prolonged bed rest is not recommended as it may increase the risk of thromboembolic complications.
2. Thromboprophylaxis should be considered for women whose mobility is reduced due to PDPH.
3. Encourage fluid intake to maintain adequate hydration.
4. Offer simple oral analgesia such as paracetamol, weak opioids and NSAIDs if not contraindicated.
5. Stronger opioids such as morphine or oxycodone may be offered but treatment should usually be limited to <72 h duration.
6. Caffeine may be offered but limited to 24 h duration, with a maximum dose of 900 mg (200 mg maximum in breastfeeding women).
7. Offer an epidural blood patch (EBP) when symptoms affect daily living and care of the baby (a guide for EBP management is provided in part 2).
8. Before hospital discharge, women who have experienced dural puncture with an epidural needle or PDPH should be given information on symptoms that require further medical assessment and on whom they should contact.
9. Arrangements should be made for appropriate follow-up after discharge from hospital for women who have experienced dural puncture with an epidural needle or PDPH.
10. When women experience dural puncture with an epidural needle or PDPH, the general practitioner (GP) and community midwife should be informed of treatment received and arrangements for further follow-up.

Figure 2. Summary of OAA recommendations (4)

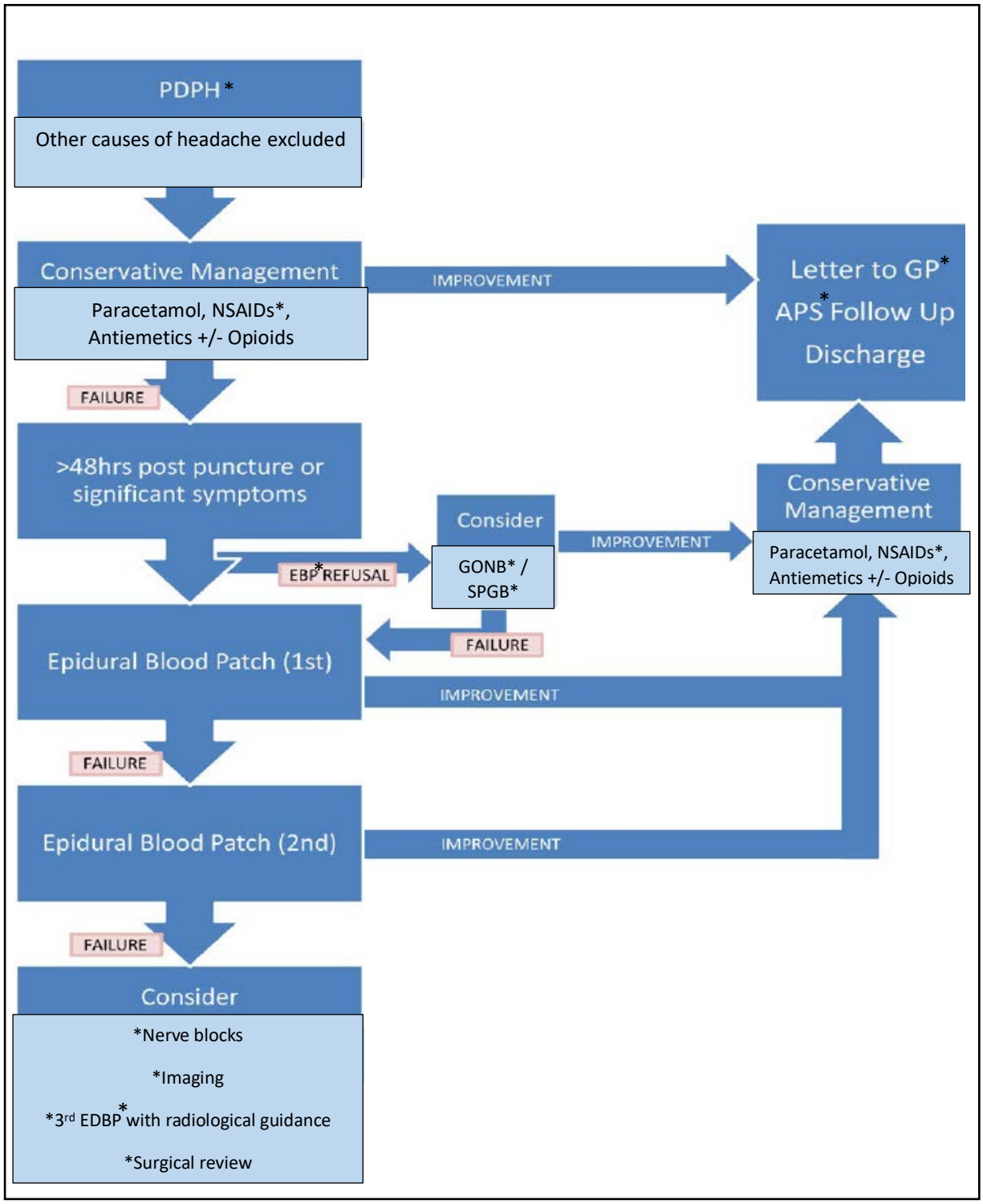


Figure 3: SAPPG PDPH Management Pathway (23)

***PDPH – Post dural puncture headache, NSAIDs – Non steroidal anti-inflammatories, GONB - Greater Occipital nerve block, SPGB – Sphenopalatine ganglion block, EDBP – Epidural blood patch, GP – General Practitioner, APS- Acute Pain Service**

1.8.1 Conservative Management

The OAA has put forward detailed guidelines for conservative management in the context of PDPH (4). The OAA recommends that any woman who is suspected of having a PDPH, should be referred to and be seen by an anaesthetist within 24 hours; thereafter they should be reviewed each day until their headache resolves (4). A full history and examination must be done to rule out other causes of headache (4). Once PDPH has been confirmed, conservative management may be trialled. This may include measures such as bed rest, oral hydration, intravenous (IV) fluid administration, and pharmacologic measures. SAPPG advise that if any neurology is present, that a neurological consult or imaging should also be obtained (23).

According to the OAA, bed rest may provide symptom relief, but it is short-lived as well as impractical for a new mother, who needs to care for her baby (4). Also, prolonged bed rest, together with the hypercoagulable state of pregnancy, may increase the risk of venous thrombosis (4, 23). SAPPG advise similarly with regards to bed rest, however, they add that the patient should position themselves in the position of most comfort (23). Both guidelines mention judicious use of anticoagulation where necessary (4, 23). Normal hydration should be maintained by either oral or IV fluids, but there is no treatment benefit from zealous fluid administration. IV fluids should only be used when oral fluids are not tolerated by the patient (4, 7, 23). There is not enough evidence to support the use of abdominal binders (4).

In terms of pharmacological management, the OAA and SAPPG both recommend that oral analgesia with paracetamol, or non-steroidal anti-inflammatory drugs (NSAIDs), should be offered to all women with PDPH (4, 23). Opioids can also be offered in the short term if the headache is not adequately relieved by simple analgesia (4). As per the OAA guidelines, there is some evidence to support oral caffeine use, however, its duration should be for a maximum of 24 hours and the total dose should not exceed 900 mg (4, 7). It is advised that a lower dose, 200 mg maximum in 24 hours, be used in breastfeeding women, especially if they have premature or low birth weight babies, as it may have effects on the neonate (4). These patients should not receive caffeinated beverages in addition to this (4).

This contrasts the recommendation of the SAPPG, which state that "recent evidence does not provide a clinically significant improvement and may cause more problems such as maternal insomnia or neonatal irritability" (23). There have also been some reports of maternal seizures after high doses of caffeine (4, 25).

There is insufficient evidence, according to the OAA, for the use of adrenocorticotropic hormone, steroids, triptans, gabapentinoids, aminophylline, and other medications (4). SAPPG, however, recommends that there is some benefit to the use of pregabalin and gabapentin (23).

1.8.2 Epidural Blood Patch (EDBP)

When conservative and pharmacological management measures fail to improve PDPH symptoms, or if the PDPH is severe and impacts on a patient's ability to perform activities of daily living (including caring for her baby), the next step to consider is an EDBP (4, 23, 24). This is the gold-standard of treatment for PDPH, and remains a foundation of therapy, despite variable techniques, volumes of blood, and waiting times being used after dural puncture (24, 26, 27).

An EDBP is an invasive procedure where a volume of blood is placed in the epidural space, and this is thought to seal the CSF leak. Variable success rates have been reported, with relief and partial relief being reported between 50–80% (24). The OAA advises that patients may require multiple EDBPs to treat their PDPH (24). EDBPs that are performed within 48 hours of dural puncture are associated with an increased need for repeat patching, but if symptoms are severe this may be required for temporary pain relief (24).

If PDPH is highly likely (for example after ADP) and suspected, based on classical symptoms, it is not necessary to perform imaging prior to doing an EDBP according to the OAA (24). However, if it is atypical or associated with neurology, imaging is advised (24).

An EDBP is not without risk of complications, which include repeated dural puncture, chronic back pain, spinal haematoma, infection, arachnoiditis, meningitis, and other neurological complications (24, 28-29). Back pain can occur in 50% of women who receive an EDBP, but it usually resolves by approximately four weeks (24). Written information regarding PDPH and EDBP should be offered to all patients to assist in the decision process and written informed consent is also advised (24).

In terms of performance technique for EDBPs, it is advised, by the OAA, that they be performed in a fully aseptic manner, at the same level or a space lower than the original injection site (24). Usually this is done with a similar technique to an epidural, except that blood is injected into the epidural space instead of an epidural catheter being inserted. Twenty millilitres of blood is the recommended volume for injection by the OAA, however, the injection of blood should be stopped before this volume is reached if the patient experiences discomfort (24).

A repeat patch may be needed if there is a return of symptoms, following an initial patch that worked or partially worked, in a patient where PDPH is likely (24). There is insufficient evidence to suggest optimal timing for repeat patches (24). Collaboration with other specialties, further workup, and imaging should be performed in cases where the first patch has no effect on symptoms, if a second patch is unsuccessful, or of there is any change in the nature of the headache or worsening of symptoms (24). According to the OAA there is insufficient evidence as to whether not performing an EDBP increases risk for chronic headaches, subdural haemorrhage, or cranial nerve palsies (24).

After an EDBP has been done, it is advised by the OAA, that the patient is reviewed by an anaesthetist within four hours of the procedure, and reviewed daily thereafter until discharge or resolution of symptoms (24). Vitals including heart rate, blood pressure, and temperature should be checked and followed up (24). Verbal and written advice detailing danger signs or whom to contact (if symptoms return) should be given to patients before discharge (24). Information should also be given to the community midwife or GP that would be managing the patient (24). The summary of EDBP management as per the OAA guidelines has been included as Appendix 1.

The SAPPG advise that the patient should remain supine for 2 hours after the patch is performed and that they may be discharged after 'routine ward observations' and review by an anaesthetist (23).

1.8.3 Alternative therapies

Other therapeutic options have been described for the treatment of PDPH, but many of these have been detailed in smaller studies or case reports, which have not been critically appraised, and are considered to be of a low evidence level, according to the OAA (4). The OAA has found insufficient evidence to support the use of acupuncture, greater occipital nerve blocks (GONBs), sphenopalatine ganglion blocks (SPGBs), epidural morphine, and epidural saline infusions (4). However, the guidelines do state that a bolus of epidural saline may transiently improve symptoms due to the resultant increase in intracranial pressure, but note that there is inadequate evidence to recommend routine use (4, 24).

The SAPPG offer a different view of GONBs (Figure 4) and SPGBs (Figure 5) and recommend their use. GONB, which has been used in the treatment of other kinds of headache, involves blocking the greater occipital nerve by injecting local anaesthetic, either with a sonar-guided or a landmark-based technique. This has been shown by some studies to provide symptomatic relief to some patients with PDPH (23).

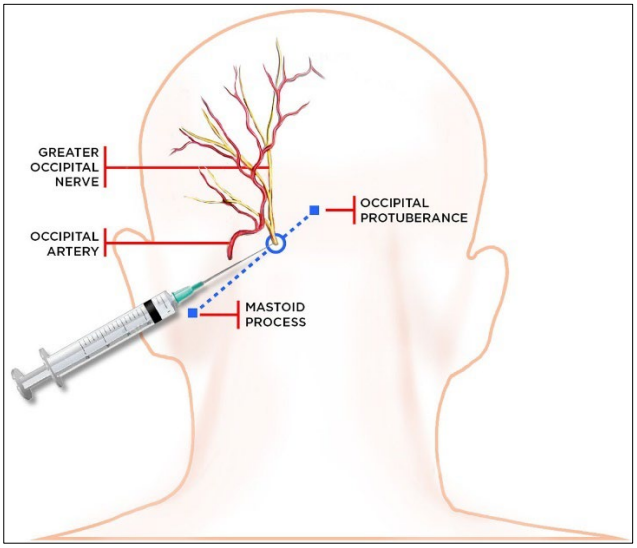


Figure 4: Landmarks for performance of GONB (25)

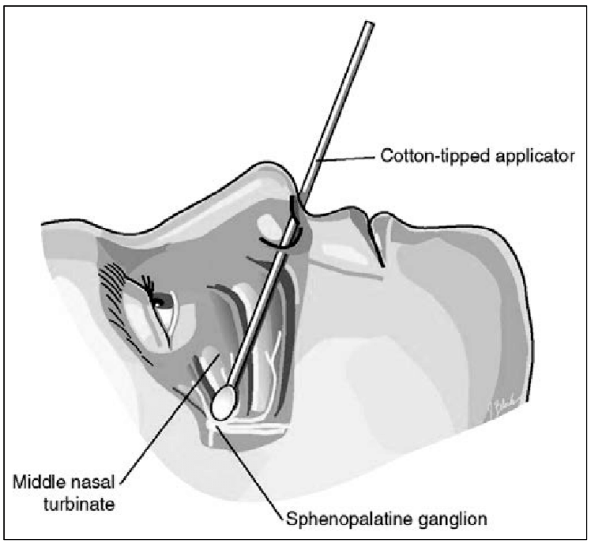


Figure 5: Performance of SPGB with a cotton swab (26)

SPGB, is also included in the SAPPG protocol for patients who decline EDBP but have failed a trial of conservative management (23). It is less invasive than an EDBP and involves the placement of local anaesthetic-soaked swabs into the nasopharynx, where the local anaesthetic is mucosally absorbed and blocks the sphenopalatine ganglion. The SPGB has been shown to have efficacy in the treatment of PDPH in some case series studies, but at the time of publishing there were no randomized control trials for SPGB in the treatment for PDPH (4, 32, 33).

The OAA reports that there is inadequate evidence or safety data to support the use of intra-epidural fibrin glue, gelatin, hydroxy-ethyl starches, or dextrans (4). The SAPPG has a place in its protocol for surgical review or intervention for dural repair in the case of refractory headache, where other causes have been excluded and a significant leak is seen on imaging (23).

1.9 Studies relating to international practice

There are a small number of practice-based surveys that have been published which evaluated Israel, the United Stated of America, Canada, Scandinavia, Turkey, and the United Kingdom (UK) (29, 34-39). These studies have all been published prior to publication of the OAA and SAPPG recommendations and, as a result, mostly compare practice between countries, rather than in relation to guidelines. Pertinent findings are summarised, per study, in the paragraphs below.

Sajjad et al. (34) conducted a study in 1995, in the UK, relating to management of ADP and PDPH. At the time, 58.5% of units had a protocol to manage ADP and PDPH. If PDPH developed, 7% of units would request a white cell count and 44% a culture and sensitivity. The timing of EDBP performance after the onset of PDPH was most frequently within 24 hours (35%), thereafter within 24-48 hours (27%), at patient request (17%), amongst other time frames. A second patch would be performed most frequently within 24 hours (60%), if the first patch failed. The recommendation was made for a "written protocol for the management of dural taps and that this should ideally be a nationwide document, perhaps drawn up under the auspices of the Obstetric Anaesthetists' Association". (34)

Berger et al. (35), in 1998, reported on dural puncture management in Canada as well as the United States. If PDPH occurred after ADP, EDBP was recommended within 24 hours of diagnosis in 47% of units, but 35% of centres waited up to 48 hours before performing an EDBP. Eleven percent of centres did a white cell count before doing the EDBP. Most patients were prescribed bed rest for less than two hours post EDBP. A second EDBP would be performed if the first patch failed, and 36% would repeat it within 24 hours of the first patch, whereas 50% would repeat the patch 24-48 hours later. Commentary was made on the limited evidence available to guide management. (35)

In 2005, Baraz et al. (36) published a survey of PDPH management in the UK. Eighty five percent of the units had a written protocol for the management of ADP and 8% were in the process of writing protocols at the time the study was conducted. The management after ADP was variable, however 41% of units re-sited the catheter at another level (36).

Seventy one percent of units trialled conservative management prior to the performance of an EDBP. In terms of counselling with respect to EDBPs, in 59% of units, the complications of repeat ADP and back pain were explained to the patient, however, in 11% of units, neither complication was explained. Forty three percent of units undertook written consent for an EDBP, with the remaining 57% taking verbal consent only. Almost all clinicians would check the patient's temperature (98%) and 46% would request a white cell count before performing an EDBP. The majority of EDBPs were done in theatre (59%) and 44% of units sent blood for culture and sensitivity during the procedure. Bed rest for less than four hours was advised by 94%. Women were most frequently discharged 'within a few hours' of EDBP (36%) and 56% of units followed their patients up, with 47% having only telephonic follow up. Alternative follow up options included an outpatient follow up appointment (31%) and community midwife follow up (17%). If a second EDBP was performed, and unsuccessful, 92% would investigate further, 71% would request neurology review, 46% a computed tomography (CT) scan and 33% a magnetic resonance imaging (MRI) scan. In the discussion it was noted that 'considerable changes' have occurred in UK practice compared to the 1993 Sajjad study, and that this was likely as a result of the implementation of guidelines. In 1993, 58% of units had guidelines compared to 85% of units having guidelines in 2005. (36)

In 2008, a study evaluating the management of PDPH in Turkish practice was conducted by Gunaydin et al. (37). Sixty four percent of respondents did not have a written protocol at their hospital. In terms of ADP management, 64% of participants stated that they would re-site the catheter at another level. In terms of conservative management strategies, 42% would encourage fluid intake and prescribe analgesia or other medications. The most commonly prescribed medications included simple analgesics and weak opioids (79%), caffeine (42%) and theophylline (23%), whilst strong opioids were rarely prescribed (4%). If conservative management failed, 64% would consider EDBP; the most frequently cited waiting time before performing an EDBP was cited as >24 hours (37%). Consent for EDBP was obtained by 64% of participants, of which 35% was written and 29% was verbal. Approximately one fifth of participants counselled the patient on the risks of backache and repeat dural puncture. In terms of other investigations, 46% would check a temperature, 36% would check a white cell count, and 13% would perform a blood culture prior to performing an EDBP. (37)

The most frequently cited location for EDBP performance was the recovery room (41%) and it usually involved having an assistant such as a resident or other staff member present (74%). Monitors including ECG (58%), blood pressure (65%) and pulse oximetry (63%) were frequently used. Approximately half of the participants would advise bed rest for 2 hours post EDBP. In the event of an unsuccessful patch, 37% would consider performing a repeat EDBP, but only 6% would consider performing more than two EDBPs. If a second patch was unsuccessful, 69% would request further investigation, 52% would refer to neurology for review and CT or MRI would be requested by 24% and 28% respectively. Recommendations were made for surveys to be conducted at other centres to encourage the development of a standardised protocol. (37)

A survey conducted by Harrington et al. (28), in the United States in 2009, described management practices for PDPH (28). Respondents indicated that only 14% of institutions had protocols for managing ADP in place, but 2% were in the process of creating ADP management guidelines. ADP management strategies most frequently included re-siting an epidural at another level (74%). Only 11% of respondents indicated that their institutions had a PDPH management protocol; it was noted that those who stated that their department had a protocol, were more likely to be in an academic teaching centre. In terms of conservative management strategies for PDPH, the following were 'frequently' prescribed: aggressive oral hydration (86%), aggressive IV hydration (63%), non-opioid oral analgesia (68%), oral opioid analgesia (34%), bedrest (71%), IV caffeine (49%), IV opioids (47%), epidural saline (29%) and abdominal binders (8%). In terms of EDBP management principles, 13% would perform an EDBP within two hours of diagnosis, whereas, most commonly, practitioners would wait 24-48 hours (44%). If a second EBDP was required, 27% of participants indicated that they would perform it immediately, and 52% would wait for more than 24 hours (28). The most frequent volume injected for the patch was 16-20mls (66.8%) and the most cited period of bedrest post EDBP was 30-60 mins (46.1%). Few (5%) participants reported the use of substances other than blood. They authors concluded that "clinical practice varies widely" and that some treatment measures are used repeatedly, such as aggressive hydration, despite limited evidence of efficacy. Recommendations were made for further studies to be conducted and interventions to be instituted to guide clinical practice. (28)

Baysinger et al. (29), in 2010, assessed the management practices of anaesthetists from the United States and Canada. This study was limited by a low response rate of 19%. It found that only 13-16% of delivery centres had protocols for managing ADP. The most frequent catheter management technique after ADP involved re-siting of the catheter at a different interspace (54%). Only 39% of respondents frequently (76-100% of the time) used conservative measures to manage PDPH and the conservative measures used included: oral hydration (89%), oral NSAIDs (87%), IV or oral caffeine (85%), IV crystalloids (74%) and oral opioids (71%); bed rest (48%), ambulation as soon as possible (18%) and oral sumatriptans (12%) were used less frequently. Most participants (80%) surveyed abandoned conservative management to perform an EDBP within 24 hours. Sixty nine percent of members obtained written consent for EDBP and only 12% took a white cell count prior to doing the EDBP. With respect to volume, 11-20mls was the most frequently cited volume of blood injected (59%) and colloid was rarely used in lieu of blood, except when religious issues were noted (26%), or if blood could not be obtained (16%). Fifty nine percent of participants instructed their patients to lie supine for 1-2 hours after performance of an EDBP. Sixty percent of participants would follow their patients the day after performing an EDBP. Seventy four percent would repeat a second patch if the first patch failed, whilst 10% would consult neurology or retry conservative management strategies. If the second EDBP failed, most would consult neurology (87%) or order imaging (49% and 63% for CT and MRI respectively). The authors recommended that "adoption of standardised protocols among North American practitioners may be a good first step toward establishing multi-centre trials of large numbers of patients to determine the optimal management of ADP and PDPH in obstetric patients". (29)

Darvish et al (38), in 2011, published results of a survey which was conducted on PDPH management in Nordic countries, including Denmark, Iceland, Finland, Norway and Sweden. Results from this survey demonstrated that on average, 42% of hospitals had a written policy for managing PDPH. In terms of conservative management strategies, caffeine was more commonly prescribed in Sweden (67%) and Norway (62%), compared to Iceland (33%), Denmark (23%) and Finland (23%). Analgesic agents including simple analgesics as well as other drugs such as sumatriptans were described but not quantified. Most of the Nordic countries did not perform EDBP until 24-48 hours after diagnosis of PDPH. On average, 76% of hospitals would consider use of a second EDBP, if the first patch was unsuccessful. (38)

Imaging, such as CT or MRI scanning, was only considered prior to the performance of a 3rd EDBP and this was in 28% of hospitals surveyed. Recommendations were made regarding future randomised studies to assist in determining the correct timing and blood volume needed for EDBP performance as well as less invasive methods of managing PDPH. (38)

A survey on PDPH management at maternity hospitals in Israel was published in 2018 by Ioscovich et al. (39). The study found that 60% of centres did not have a departmental protocol for managing PDPH or performing EDBPs. Most centres (44%) reported re-siting the epidural catheter at a different level if ADP occurred. Sixty five percent of the time, the anaesthetist was informed of PDPH being present by a gynaecologist, and 30% of the time by a nurse. All PDPH cases receive analgesia, 91% of centres prescribed fluids, 74% prescribed bedrest, and 61% prescribed caffeine. Ninety six percent of centres prescribed conservative management for 24-48 hours duration. Informed consent was recorded on an EDBP consent form in 39% of centres, on a surgical consent form in 35% of centres, and on an epidural consent form in 26% of centres. Most centres performed the EDBP in the recovery unit (57%) or in theatre (35%). The EDBP was usually performed by a specialist anaesthetist or the head of the unit, or in some instances by a pain specialist. Assistance in taking blood for the patch was usually done by a registrar (70%), consultant anaesthetist (22%) or a nurse (9%). The most frequently injected volume of blood was noted to be 15-25 mls in 83% of centres, and most frequently, the patch was performed at the same level (61%) as the original procedure. Fifty six percent of centres prescribed bed rest of greater than an hour's duration after performing an EDBP and 61% of patients would be followed up after EDBP performance prior to discharge. Recommendations were made "to reach a uniform literature-based management strategy across Israeli hospitals". (39)

The results of these studies demonstrate that there is wide variation in management of PDPH with respect to almost all stages of care (28-29, 34-39). Furthermore, practice even within the same country varies over time in relation to emerging evidence and in some instances, the implementation of guidelines (29, 35-36). A marked disparity in the frequency of protocol-use for PDPH management is also demonstrated by these studies with 8-14% of North American respondents having accessed a protocol to manage PDPH, compared to 21% of Israeli and 85% of respondents in the UK (29, 36). Recommendations were made towards the creation and implementation of more evidence-based strategies, guidelines, and protocols (29, 39).

1.10 Studies relating to local practice

There are no published studies which document current practices with respect to PDPH management in South Africa, and the awareness of internationally recommended guidelines among South African anaesthetists is also unknown. Furthermore, management practices of members of the Wits Department of Anaesthesiology are undetermined. Whilst there is an indication of the practices of high-income countries from published studies, local management of PDPH in South Africa may differ due to limitations relating to infrastructure and staffing.

A study which audited the epidural service in a South African academic hospital showed a high incidence of PDPH, but that no epidural blood patches were performed for treatment, despite this being considered the gold-standard of treatment (13, 24). Other details relating to PDPH management were not specified.

1.11 Importance of guidelines and clinical pathways

Anaesthetists may be overwhelmed with the knowledge and research available, and may not know what is considered best practice, especially if there are no specific guidelines available at the institutions where they are employed. According to Lavelle et al. (40) “the sheer volume of new medical knowledge makes it extremely difficult for clinicians to stay up to date and incorporate new best practices into patient care”.

Clinical guidelines and clinical pathways may assist clinicians with patient management decisions. Clinical practice guidelines are defined by the Institute of Medicine as ‘statements that include recommendations intended to optimise patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options’ (41). A clinical pathway is defined as “a detailed plan of care for a well-defined group of patients, which translates guidelines, evidence, and expert consensus opinion into local care and is a result of multidisciplinary work” (40).

Well-designed clinical pathways provide benefits to both patients and providers as they can minimise unnecessary testing, decrease admission rates, reduce error, improve documentation, and allow for shorter hospital stays (40, 42). Clinical pathways may ultimately result in improved patient care and reduced healthcare costs (40).

Although the South African Society of Anaesthesiologists, and the South African Society of Regional Anaesthesia, have guidelines for clinical practice relating to anaesthesia and regional anaesthesia, these were published in 2018 and 2016 respectively and neither contain specific recommendations with respect to the detailed management of PDPH (43). The 2016 guidelines have also not subsequently undergone revision, despite the recommended median lifespan of clinical guidelines being five years (44). Specific South African guidelines are required to ensure best practice based on available local resources, as well as practitioner and patient preferences (45).

1.12 Summary and recommendation for study

PDPH is a common consequence of spinal and epidural anaesthesia. It is essential that PDPH is identified and managed appropriately as it is associated with significant maternal morbidity, prolonged hospital stay, and increased healthcare costs (1, 2, 7, 8, 17, 18, 20).

Although international guidelines for the management of PDPH are available, it has been demonstrated that internationally there is wide variation in PDPH management practices. There are no published studies which document current practices, nor are there available guidelines, with respect to PDPH management in South Africa. The awareness of internationally recommended guidelines among South African anaesthetists is also unknown. Local management of PDPH in South Africa may differ from that internationally due to limitations relating to infrastructure and staffing.

Specific South African guidelines would assist with ensuring best practice based on available local resources, as well as practitioner and patient preferences (45). Regular assessment of practices of health care providers is essential to inform and enable the creation of locally appropriate standardised processes, such as clinical pathways, which assist in the delivery of high-quality care that is evidence-based (40, 44).

This study aims to describe the current PDPH management practices of Wits anaesthetists, with the aim of assisting to inform the development of future local management guidelines or clinical pathways.

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Section 3: Draft Article

A survey of postdural puncture headache management practices within an academic department

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Keywords: postdural puncture headache, practice, anaesthetist, management, protocol, guidelines

Abstract

Background

Postdural puncture headache (PDPH) is a common consequence of neuraxial anaesthesia, especially among parturients, in whom it is associated with maternal morbidity, prolonged hospital stay, and increased healthcare costs. Although international guidelines for PDPH management are available, variable management practices exist. There are no published studies which document current practices, nor guidelines available, with respect to PDPH management in South Africa. This study aims to describe PDPH management practices within the Wits Department of Anaesthesiology, which may assist in future local guideline or protocol development.

Methods

An electronic questionnaire was distributed to the Wits Department of Anaesthesiology. The survey instrument was developed following a literature review targeting recent evidence based PDPH management guidelines, including the Obstetric Anaesthetists Association (OAA) guidelines from 2018, after which it was reviewed for content and face validity. Participant responses were then compared to the OAA guidelines, which were considered the standard of practice. A score relating to this was determined and compared to demographic variables to assess for possible correlations.

Results

Participants' practice with respect to conservative management strategies and the performance of EDBPs was in keeping with the OAA guidelines, despite evidence of limited provider experience with performing these procedures, as well as the lack of available departmental guidelines. Ninety six percent of anaesthetists perceived they would benefit from the institution of formal guidelines.

Conclusions

Management practices for the treatment of PDPH among anaesthetists within the Wits circuit are variable, but generally consistent with current international guidelines, however, limited experience in treating PDPH has been demonstrated. The development, and institution, of formal guidelines to assist in the management of PDPH is recommended, as well as continuous medical education of staff, to ensure good patient outcomes. (Word Count:282)

Introduction

A postdural puncture headache (PDPH) is defined by the International Headache Society as a headache, occurring within 5 days of a lumbar puncture, which is caused by cerebrospinal fluid leakage through the dura and is usually accompanied by neck stiffness and/or subjective hearing problems.[1] PDPH is a common consequence of neuraxial anaesthesia, with an incidence of approximately 1%, but as high as 88% after accidental dural puncture (ADP) during the performance of an epidural with the use of a 16 G Tuohy needle.[2-3] It typically resolves spontaneously within 2 weeks, or after sealing of the leak with an autologous epidural blood patch (EDBP).[1]

PDPH is associated with morbidity and mortality, especially in the obstetric patient population in whom neuraxial procedures are commonly performed. The effects of PDPH can be debilitating and result in poor maternal-infant bonding, decreased ambulation, increased duration of hospital-stay, recurrent hospital visits, and increased hospital costs.[3] It is also associated with chronic headaches, as well as subdural haemorrhages, which can result from tearing of the intracerebral bridging veins secondary to significant intracranial hypotension.[4]

Literature available from South African academic hospitals suggests that the rate of PDPH may be two to three times higher than that in high income countries.[5] This may be related to low epidural rates and poor skill development.[6] A study performed in a South African academic hospital auditing epidural practice showed that no EDBPs were being performed for the treatment of PDPH, despite this being considered the gold-standard of treatment.[5, 7]

Internationally, there are published practice-based surveys which have evaluated countries including Israel, the United Stated of America, and the United Kingdom. These studies demonstrate that there is wide variation in the management of PDPH.[8-12] There is little consensus with regards to the best approach to managing PDPH, and much of the existing advice is ‘based on very little robust scientific evidence’.[7] Recent guidelines on managing PDPH in the obstetric setting have been put forward by the Obstetric Anaesthetists’ Association (OAA) in 2018 and there are also recently published Australian guidelines from 2017, both of which are based on a review of the literature and expert opinion.[7, 13]

At present, there are no guidelines which have been endorsed by the South African Society of Anaesthesiologists, nor is there a recommended protocol or guideline available from the University of the Witwatersrand's (Wits) Department of Anaesthesiology.

There are no published studies which document current management practices with respect to PDPH in South Africa and the South African anaesthetists' management of PDPH may be different to those demonstrated internationally due to limitations relating to infrastructure and staffing. Management practices of the Wits Department of Anaesthesiology are also unknown. Therefore, this study aims to describe the PDPH management practices of Wits anaesthetists, which may, in future, assist to inform the development of local management guidelines or clinical pathways.

Methods

A prospective, descriptive, contextual, cross-sectional study was performed using a self-administered questionnaire. The survey instrument was developed following a literature review targeting the most recent evidence-based PDPH management guidelines, particularly those from the OAA, after which it was assessed for content and face validity by 10 qualified anaesthetists with an interest in obstetric/regional anaesthesia. The survey consists of 40 questions subdivided into seven sections (Appendix 2).

Ethics approval was obtained from the Wits Human Research Ethics Committee (Medical), approval number: M200603. Permission was acquired from the relevant authorities, after which the voluntary and anonymous questionnaire, done via the REDCap® platform, was electronically distributed to all members of the Wits Department of Anaesthesiology on 3 occasions. The department is comprised of 214 anaesthetists: 58 consultants, 12 career medical officers, 102 registrars, and 42 medical officers. After consultation with a biostatistician, it was determined that a minimum response rate of 138 (66%) was required based on a margin of error of 5%, a confidence level of 95%, and a response distribution of 50%.

Data were downloaded from REDCap® into a Microsoft Excel® spreadsheet and then analysed using Statistica™ and STATA™ software. Categorical variables were summarised as frequencies and percentages, continuous variables were summarised as medians and interquartile ranges and Chi square tests were performed for inter-variable comparison.

Results were then compared to the OAA guideline recommendations and an additional score relating to 'correct practice' was made. Points were allocated to various questions and certain responses were indicated as being correct or incorrect based on their compatibility with the 2018 OAA guidelines. These were given points of 1 or 0 respectively. Only questions where the anaesthetist had a degree of choice/control over the result were included in this series (Questions 17, 19, 22-24, 26-33, 35-37, 39; Appendix 3). The questions incorporated totalled 37 points, and a score of more than or equal to 26 points (70%), was deemed to be associated with 'correct practice'. This score was determined and validated by the modified-Angoff method in consultation with 10 qualified anaesthetists. A comparison between 'correct practice' and the demographic section variables was performed with the use of Chi Square tests to assess for correlation. A p value of < 0.05 was considered statistically significant.

Calculation of an Alpha Cronbach coefficient, as an index of reliability for the questions included in the assessment of correct practice, was performed with the aid of STATA™ software. The calculated Cronbach alpha coefficient for the survey questions included in the assessment of 'correct practice' was 0.65, demonstrating an acceptable reliability. [14]

Results

The response rate for the survey was 68% (145/214), but only 140 surveys were included as five had large amounts of missing data. The demographic data for the respondent anaesthetists are presented in Table 1.

Table 1: Demographic characteristics of participants

Characteristic	n (%)
Age in years	**N=140**
25–29	16 (11%)
30–39	94 (67%)
40–49	18 (13%)
50–59	8 (6%)
≥60	4 (3%)
Gender	**N=139**
Male	53 (38%)
Female	86 (61%)
Years of anaesthetic experience	**N=140**
< 1 Year	1 (1%)
1-2 Years	19 (14%)
3-5 Years	60 (43%)
6-9 Years	31 (22%)
≥10 Years	29 (21%)
Rank	**N=140**
Medical Officer	16 (11%)
Junior Registrar - 1st and 2nd year	30 (21%)
Senior Registrar - 3rd, 4th and subsequent years	53 (38%)
Consultant (This includes Career Medical Officers who have > 10 Years' experience)	41 (29%)

Seventy nine percent of participants were unaware of guidelines for the management of PDPH (109/138), however, 96% (134/139) perceived that they would benefit from the institution of formal guidelines. The participants' responses with respect to the follow up of neuraxial anaesthesia and accidental dural puncture are presented in Table 2 below.

Table 2: Follow up of neuraxials and ADP

Follow up of patients who receive neuraxial anaesthesia the day after the procedure is performed	
Spinal Anaesthesia	**N = 140**
Always	3 (2%)
Often	7 (5%)
Rarely	80 (57%)
Never	50 (36%)
Epidural Anaesthesia	**N = 139**
Always	52 (37%)
Often	44 (32%)
Rarely	29 (21%)
Never	14 (10%)
Reasons why patients are not followed up	**N = 126**
Logistically not plausible	78 (62%)
Someone else will report PDPH to me	29 (23%)
I do not have time	15 (12%)
Not concerned about PDPH	2 (2%)
Other	2 (2%)
Previously performed an epidural where ADP has occurred	**N = 139**
Yes	65 (47%)
No	69 (50%)
Never performed an epidural	5 (4%)
Initial management of ADP	**N = 139**
Remove needle and try at another level	97 (70%)
Abandon procedure entirely	29 (21%)
Prophylactic epidural blood patch	3 (2%)
Feed catheter intrathecally & use in intrathecal space	8 (6%)
Prophylactic saline intra-epidurally	2 (1%)
Follow up of patients when ADP has occurred	**N = 138**
Yes	119 (86%)
No	15 (11%)
Never performed an epidural	4 (3%)

Approximately one third (34%; 47/140) of participants indicated that they had never been involved in the management of patient with PDPH and more than half of respondents (56%, 77/138) felt that they had insufficient knowledge and expertise to manage a patient with PDPH. The PDPH general management and conservative management practices of participants are detailed in Table 3 and Table 4.

The participants' management practices with respect to the performance of EDBPs are detailed in Table 5. Eighty eight percent (89/101) of registrars or medical officers indicated that they would want supervision during the performance of an EDBP. Fifty seven percent (79/138) of participants indicated that they had no experience of having performed a second EDBP in the same patient if the first one failed.

In terms of other possible treatment modalities, that participants could use as part of their management strategy, only nine percent of participants (12/138) indicated they had previously performed a SPGB, and two thirds of these participants (8/12) had performed between two to five SPGBs.

With regards to assessing for 'correct practice', 94% (132/140) of anaesthetists surveyed obtained a score of more than or equal to 70% by having selected options which aligned with the OAA management guidelines. There was no statistically significant association between any of the demographic characteristics and knowledge of correct practice (Table 6).

Table 3: General PDPH management

How participants become aware or are informed that there is a patient with suspected PDPH (multiple options could be selected)	**N = 140**
Informed by a member of the obstetric team	117 (84%)
Informed by ward nursing staff	21 (15%)
Become aware during follow up themselves	27 (19%)
Report from another anaesthetist	43 (31%)
Other	9 (6%)
Actions taken on the first day of management in a patient with suspected PDPH (multiple options could be selected)	**N = 140**
History and examination	135 (96%)
Monitor and review of the patient's temperature	106 (76%)
Blood tests	58 (41%)
CT scan	2 (1%)
Conservative management (IV fluids, analgesia, bed rest)	136 (97%)
Sphenopalatine ganglion block	10 (7%)
Epidural blood patch	5 (4%)
Physician/Neurology consult	5 (4%)
Other	6 (4%)
Blood tests ordered during the initial work-up of PDPH patients (multiple options could be selected)	**N = 140**
None	37 (26%)
FBC	98 (70%)
U and E	48 (34%)
CRP	82 (59%)
Blood Cultures	22 (16%)
Other	4 (3%)

Table 4: Conservative management strategies

Prescription of oral fluids	**N=127**
Yes	117 (92%)
No	10 (8%)
Prescription of IV fluids	**N = 127**
Yes	102 (80%)
No	25 (20%)
Prescription of bed rest	**N = 138**
Yes	126 (91%)
No	12 (8%)
Medication prescribed for PDPH (multiple options could be selected)	**N = 140**
Paracetamol	138 (99%)
NSAIDs	103 (74%)
Opioids	40 (29%)
Caffeine	125 (89%)
Gabapentinoids	5 (4%)
Other	1 (1%)
Duration of time that conservative management is trialled	**N = 140**
< 24 hours	21 (15%)
24-48 hours	108 (77%)
49 -72 hours	9 (6%)
> 72 hours	1 (1%)
No conservative management – immediate performance of an EDBP	1 (1%)
Next step taken if conservative management fails	**N = 139**
Epidural Blood Patch	125 (90%)
Sphenopalatine Ganglion Block	13 (9%)
Epidural patch with other substances	1 (1%)
Greater Occipital Nerve Block	0 (0%)

Table 5: Participants experience and management of EDBP

Number of EDBP performed previously	**N = 140**
0	77 (55%)
1	25 (18%)
2 to 5	29 (21%)
≥6	8 (6%)
Complications relating to EDBP that participants routinely counsel patients on (multiple options could be selected)	**N = 140**
Infection	127 (91%)
Repeat dural puncture	92 (66%)
Spinal haematoma ± paralysis	70 (50%)
Backache	113 (81%)
Nerve Damage	66 (47%)
Failure of EDBP	121 (86%)
Obtain written consent for the EDBP	**N = 139**
Yes	128 (92%)
Locations where EDBPs are performed	**N = 139**
Minor procedure room	38 (27%)
Operating theatre	83 (60%)
The ward	17 (12%)
Other	1 (1%)
Monitors routinely applied when performing an EDBP (Multiple options could be selected)	**N = 140**
ECG	123 (88%)
NIBP	136 (97%)
Pulse Oximetry	135 (96%)
Individual responsible for drawing the sterile blood for EDBP	**N = 139**
Fellow anaesthetist	116 (83%)
Participant themself	15 (11%)
Other	6 (4%)
Surgeon	1 (1%)
Nurse	1 (1%)

Table 6: Factors associated with correct practice

Variable	Categories	Correct practice n (%)	Incorrect practice n (%)	p-value
Age (N =140)	25 – 29	16 (12%)	0 (%)	0.70
	30 – 39	87 (66%)	7 (88%)	
	40 – 49	17 (13%)	1 (12%)	
	>50	12 (9%)	0 (0%)	
Total		132 (100%)	8 (100%)	
Gender (N =139)	Male	82 (63%)	4 (50%)	0.48
	Female	49 (37%)	4 (50%)	
Total		131 (100%)	8 (100%)	
Years of Anaesthetic Experience (N =140)	< 3 Years	18 (14%)	2 (25%)	0.18
	3 – 5 Years	58 (44%)	2 (25%)	
	6 – 9 Years	27 (20%)	4 (50%)	
	≥ 10 Years	29 (22%)	0 (0%)	
Total		132 (100%)	8 (100%)	
Rank (N =140)	Medical officer	16 (12%)	0 (0%)	0.17
	Junior Registrar	26 (20%)	4 (50%)	
	Senior Registrar	50 (38%)	3 (38%)	
	Consultant	40 (30%)	1 (12%)	
Total		132 (100%)	8 (100%)	

Discussion

This is the first published South African study that focuses on management practices for the treatment of PDPH. The results of this study show that whilst 94% of participants had scores which were considered to reflect 'correct practice' (in terms of the OAA guidelines), more than 78% were unaware of any PDPH management guidelines. However, almost all participants (96%) perceived that they would benefit from guideline implementation. More than half of anaesthetists surveyed (56%) felt they had insufficient knowledge or expertise to manage a patient with PDPH appropriately. The desire for guidelines may therefore reflect poor confidence levels of staff members regarding PDPH management; this may be the result of inexperience as more than a third of participants had never managed PDPH and more than half (55%) had never performed an EDBP.

The low levels of EDBP performance and practical experience may relate to low epidural rates in Gauteng and the associated decreased number of ADPs, despite South Africa having a two to three times higher rate of PDPH compared to high income countries.[5, 6] Data from a study by Jacobs-Martin et al.[5] showed that there were no EDBP performed within one year at Tygerberg Academic Hospital in South Africa. This contrasts with other countries such as the United States, where as many as 30 patches may be done at one institution per year.[15]

Within those participants who had done EDBP(s), only 6% had performed more than five EDBPs, the majority of which were consultants. Practical competency, with a 90% success rate, when performing regional techniques, such as spinals and epidurals, requires a minimum of 45-60 procedures be performed.[16]. The data in this study suggests that very few members of the department have sufficient practical experience to be considered adequate supervisors for performance of EDBPs. Of the registrars that participated, 12% stated they would not be supervised when performing an EDBP - this practice is contrary to the recommendation made by the OAA guidelines, and has the potential to put patients at higher risk of morbidity.[17]

Contrary to both the OAA and South Australian Perinatal Practice Guidelines (SAPPG) recommendations, most study participants indicated that written information regarding PDPH itself (77%) as well as its treatment options (97%) was not provided to patients.[7, 13]

This may highlight a shortcoming in our system as written information being made available to patients has the potential to improve patient knowledge, confidence, satisfaction, adherence to recommended care, as well as doctor-patient communication scores.[18-20]

The results of this study also show a lack of patient follow up after neuraxial procedures, including those with ADP. This is most concerning as ADP is the largest risk factor for PDPH development.[4] This lack of follow up is contrary to the OAA guidelines and could result in patients with PDPH being missed, which may result in poor patient satisfaction, morbidity, and mortality.[7, 21]

The most common reason for lack of follow up of neuraxials was cited as logistics (62%); this requires further investigation to establish what the specific logistical issues are and to develop and implement strategies to facilitate better management practices. This coupled with 77% of participants indicating that they were unaware of a mechanism for reporting PDPH would likely result in both inadequate identification of patients with PDPH and poor reporting thereof. Similarly to an Israeli study, patients who are identified with PDPH are most often brought to the department's attention by a member of the obstetric team rather than by an anaesthetist.[10] Anecdotally, this lack of follow up and reporting, may be contributing to the lower rates of PDPH management in our setting, which this study has shown. However, further investigation is necessary to confirm this supposition.

In general, the findings pertaining to conservative management of PDPH were in keeping with the OAA guidelines. Most anaesthetists surveyed would provide oral and intravenous fluids, where the OAA guidelines advise the maintenance of normal hydration.[7] Also, similarly to other countries, most participating anaesthetists would prescribe simple analgesia and NSAIDs, whereas few opted for gabapentinoids or other medications not presently supported by the OAA guidelines.[7, 9, 11, 22]

Caffeine prescription, which has shown benefit according to the OAA guidelines, was similar to the North American survey population, but more than double that from a UK survey, perhaps as a result of existing reports of seizures after caffeine use.[7, 9, 11] More anaesthetists in our survey advised bed rest compared to North American anaesthetists: 92% versus 48%, but the duration advised was variable.[9] This at odds with the OAA guidelines, which advise that whilst many women gain transient relief from bed rest, prolonged bed rest is not recommended as it may increase the risk for venous thromboembolism.[7]

In addition, similarly to the findings from the Israeli, UK and Nordic surveys, most anaesthetists (90%) would proceed to perform an EDBP in the event of conservative management being insufficient and most within the time frame of 24-48 hours.[10, 11, 22]

This markedly contrasts the findings of the North American Survey by Baysinger et al.[9] which demonstrated that most (81%) would perform an EDBP within 24 hours and this likely being due to feelings that 'conservative measures were largely ineffective'. This, however, differs from the OAA recommendations, which specify that patients should be informed that there is a lower efficacy in treating PDPH with an EDBP, and a higher need for repeat patch, if done within the first 48 hours of dural puncture.[7]

Of note, a small percentage (9%) of participants performed SPGB, instead of EDBP, as the next step if conservative management failed. Although this is not presently supported by the current OAA guidelines, it should not be fully discounted as it has been shown to have efficacy in treating PDPH in smaller case reports and case series studies as both a temporary method of pain relief or a curative treatment.[23-24] In a resource poor environment, where theatre time is in high demand, a relatively quick, easy, safe and inexpensive technique such as this may need to be considered.[23-24] It could also be considered in patients who decline or have contraindications to EDBP, which is in keeping with the SAPPG recommendations.[13] However, further high-level evidence is required to establish a more accurate efficacy with respect to this modality of treatment if it is to be included in local guidelines.

With regards to the use of EDBPs, it is concerning that whilst 92% of participants said they would obtain written consent, nearly half of participants did not counsel patients about the risks of repeat dural puncture (44%), the risks of haematoma and paralysis (50%), nor the risk of nerve damage (53%). These are all necessary as part of an appropriately informed consent, as per Health Professions Council South Africa good practice guidelines.[25] The Medical Protection Society has stated that the 'presence of a signed consent form does not in itself prove valid consent to treatment; the important factors will always be the quality, extent and accuracy of the information given beforehand'.[26] Whilst consent is being obtained, it is inadequate and thus increases the risk potential litigation.[27]

Monitoring, sterility, assistance during the EDBP procedure itself, as well as volume of blood injected, were generally in keeping with the OAA guidelines as well as studies from the United States.[7-9] Sixty percent of anaesthetists surveyed would perform the EDBP in theatre, similarly to the results from Baraz et al[11] in the UK.

This contrasts with findings from the Turkish study by Gunyadin et al[28], which cited the most frequent location for EDBP performance being the recovery room, as well as a much lower use of monitors including as ECG (58%), non-invasive blood pressure (65%) and pulse oximetry (63%) compared to this study. The most frequently cited volume of blood for injection during the EDBP procedure, however, was cited as 20 mls, which is similar to the results from Israeli, Turkish and North American studies. [8-10, 28]

Indications for imaging of the brain and spinal cord were variable, but consensus was achieved on focal signs, decreased level of consciousness, and signs and symptoms suggestive of meningitis (see supplementary table 1). However, other accepted indications, such as tinnitus/vertigo and a failed 2nd EDBP, were not commonly selected despite being indicated as part of the OAA guidelines. This could result in patients with other intracranial pathology being missed and associated morbidity and mortality.[7, 21, 27] Although the OAA does not recommend imaging after a failed first patch, 42% of participants selected this option and a further 21% indicated that they would request imaging if symptoms did not resolve after 2 days of conservative management. These practices would result in inappropriate use of a limited resource. A protocol with indications for imaging may be beneficial to ensure correct patient care and utilisation of scare resources.

Most anaesthetists (87%) did not follow patients up after discharge with PDPH, despite this being part of the OAA guidelines.[7] This also contrasts with the findings from a UK study, where 56% of patients were followed up after discharge.[11] The institution of departmental guidelines may assist with this by detailing a follow up protocol for patients. [18, 19]

Internationally, there is variable access to and application of guidelines, with a written policy for PDPH management being found to be available in 85% of UK maternity units, 42% of institutions within Nordic countries, and between 8-14% in various North American institutions.[8-9, 11-12, 22] There have been significant changes noted in the management of various aspects of ADP and PDPH between 1993 and 2005 in the UK surveys, which have been attributed to the implementation of guidelines. [11] The changes noted are in keeping with newer recommendations regarding the use of intrathecal catheters, timing of conservative management and performance of EDBPs.[7, 13]

Many of the international studies detailing PDPH management practices have put forth recommendations for the creation and institution of guidelines pertaining to PDPH management.[8-12] Guidelines have been shown to improve patient outcomes, result in standardisation of patient care, and promote distributive justice.[29, 30] At present, the OAA guidelines from 2018 represent the most recent evidence based recommendations for PDPH, however specific South African guidelines are required to ensure best practice based on available local resources, as well as practitioner and patients' management preferences.

Limitations

This study is contextual in nature and the results represent only the practices of Wits anaesthetists at the time of data collection. The findings cannot necessarily be generalised to other departments or institutions. Also, the primary objective of this study was to describe management practices for PDPH and the questionnaire was primarily designed around this task. The study was not principally designed to investigate or report on the objective of 'correct practice' or to assess competence. Therefore, results relating to "correct practice" should be interpreted in this context.

Conclusion

Currently there are no specific South African guidelines or Wits departmental guidelines pertaining to the management of PDPH. There is some variation of practice when it comes to the management of PDPH by anaesthetists in the department, however, despite this, most anaesthetists surveyed demonstrated correct practice with regards to PDPH management when compared to the OAA guidelines.

Confidence levels regarding management of PDPH were poor in more than half the anaesthetists surveyed. This may reflect the lack of clinical experience among participants. Most anaesthetists surveyed perceived that they would benefit from the implementation of guidelines. The development, and institution of formal guidelines to assist in the management of PDPH, as well as continuous medical education of staff with respect to the content of such protocols is recommended to ensure good patient outcomes.

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(Word Count: 3153)

Supplementary Tables

Supplementary Table 1: Indications for CT brain and spinal cord imaging (N=140)

	n (%)
Part of routine initial work-up	3 (2%)
Symptoms not resolving after a day of conservative management	17 (12%)
Symptoms not resolving after 2 days of conservative management	30 (21%)
Failed 1st patch	59 (42%)
Failed 2nd patch	38 (27%)
Tinnitus and/or vertigo	65 (46%)
Focal Signs/ Other neurological signs	133 (95%)
Decreased level of consciousness	124 (89%)
Symptoms of meningitis	97 (69%)

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Section 4: Proposal

A Survey of Postdural Puncture Headache Management Practices within an Academic Department

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4.1 Introduction

A postdural puncture headache (PDPH) is defined by the International Headache Society as a headache occurring within 5 days of a lumbar puncture, which is caused by cerebrospinal fluid (CSF) leakage through the dural puncture, and is usually accompanied by neck stiffness and/or subjective hearing problems. It usually remits spontaneously within 2 weeks, or after sealing of the leak with autologous epidural lumbar patch (1). It is typically worse on movement, especially from the supine to upright position (2). The pathophysiology of PDPH remains unclear, but it is thought to be caused by a CSF leak when the rate of leakage exceeds that of production. This results in intracranial hypotension and traction on the meninges, which causes parasympathetic vasodilation of the meningeal blood vessels and the resultant headache (2, 3).

PDPH is a fairly common consequence of spinal and epidural anaesthesia, with an incidence of approximately 1% (4, 5). The incidence of PDPH is influenced by the size and type of needle used. Smaller pencil point needles are associated with a lower incidence of PDPH compared to larger or cutting needles (4, 6). There is a 0.5–2% incidence of PDPH after spinal anaesthesia using small pencil point needles (4, 7). There is a much higher incidence of PDPH after accidental dural puncture (ADP) during the performance of an epidural, and the risk may even be as high as 88% with the use of a 16G Tuohy needle (4). Therefore, spinal and epidural anaesthesia, and ADP are significant causes of PDPH.

PDPH can be debilitating and result in poor maternal-baby interaction, decreased ambulation, increased duration of hospital-stay, recurrent hospital visits, and increased hospital costs (5). It has been linked to chronic headaches, as well as more serious morbidity such as subdural haemorrhage, which can result from tearing of the intracerebral bridging veins secondary to significant intracranial hypotension; this is associated with higher morbidity and mortality (25).

Literature available from South African academic hospitals suggests that the rate of PDPH may be two to three times higher than that in high income countries (8, 9). This may be related to low epidural rates and poor skill development. Management of PDPH in South Africa may also differ from that in high income countries as a result of limitations relating to infrastructure and staffing. A study performed in a South African academic hospital showed that no epidural blood patches (EDBPs) were being performed for the treatment of PDPH, despite this being considered the gold-standard of treatment (8, 10). There are no published studies which document current practices with respect to PDPH management in South Africa. Furthermore, management practices of members of the University of the Witwatersrand (Wits) Department of Anaesthesiology are unknown.

There is little consensus with regards to the best approach to managing PDPH, and much of the existing advice on the management of PDPH is "based on very little robust scientific evidence" (11). Recent guidelines have been put forward by the Obstetric Anaesthetists' Association (OAA) and there are also recently published Australian guidelines that are available (10-12). Both guidelines are based on a review of the literature and expert opinion. The guidelines discuss some of the modalities of treatment, including conservative and pharmacological management, invasive procedures, epidural fluid administration, epidural blood patches and miscellaneous treatments including nerve blocks (10-12).

The OAA recommends that any woman who is suspected of having a PDPH, should be referred to and be seen by an anaesthetist within 24 hours. Women who experience PDPH should be reviewed by an anaesthetist daily until complete headache resolution occurs (11). A full history and examination must be undertaken to exclude other causes of headache. Once PDPH has been confirmed, conservative management may be trialled; this includes bed rest, oral hydration, intravenous (IV) fluid administration and/or use of abdominal binders. Bed rest may provide symptom relief, but it is short-lived; furthermore, if bed rest is prolonged, it may increase risk of thromboembolic complications (11). Normal hydration should be maintained by either oral or IV fluids, but there is no treatment benefit from excessive fluid administration (5). There is not enough evidence to support the use of abdominal binders (11).

Pharmacological management, including simple oral analgesia with paracetamol or non-steroidal anti-inflammatory drugs, should be offered to all women with PDPH.

Opioids can also be offered short term if the headache is not adequately covered by simple analgesia (11). There is some evidence to support oral caffeine use (300mg per dose), for a maximum of 24 hours; the total dose should not exceed 900mg (5, 11). It is advised that a lower dose (200mg maximum in 24 hours) be used in women who are breastfeeding, especially if they have premature babies or low birth weight babies. There is insufficient evidence according to the OAA for the use of adrenocorticotropic hormone, steroids, triptans, gabapentinoids, aminophylline and other medications (11).

When conservative management and pharmacological management fail to improve the PDPH symptoms, the next step is to consider invasive procedures such as the EDBP. The OAA has found insufficient evidence to support the use of acupuncture, greater occipital nerve blocks, sphenopalatine ganglion blocks (SPGBs), epidural morphine, and epidural saline infusions (11). It also reports that there is inadequate evidence or safety data to support the use of intra-epidural fibrin glue, gelatin, hydroxy-ethyl starches or dextrans (11).

The EDBP is the gold-standard of treatment for PDPH, and seems to remain the foundation of treatment, despite variable techniques, volumes of blood and waiting times being used after dural puncture (13, 14). An EDBP is an invasive procedure whereby a volume of blood is placed in the epidural space. This is thought to seal the CSF leak. It should be considered if the patient has severe symptoms that interfere with activities of daily living (10). Variable success rates have been reported over the years, with relief and partial relief being reported between 50–80% (10). An EDBP is not without risk of complications, which include repeated dural puncture, chronic back pain, spinal haematoma, infection, arachnoiditis, meningitis, and other neurological complications (10). The OAA advises that patients may require multiple EDBPs to treat their PDPH. EDBPs that are performed within 48 hours of dural puncture are associated with an increased need for repeat patching, but if symptoms are severe this may be required for temporary pain relief (10).

In terms of performance technique for EDBPs, it is advised by the OAA that they be performed in a fully aseptic manner, at the same level or a space lower than the original site, with 20mls of blood. However, the injection of blood should be stopped before this volume is reached if the patient experiences discomfort (10). There is inadequate evidence to support routine IV antibiotics (10).

A repeat patch may be necessary if there is a return of symptoms following an initial patch that worked (10). Collaboration with other specialities and further workup and imaging should be performed in cases where the first patch has no effect on symptoms, or if a second patch is unsuccessful (10).

The above-mentioned practices are all part of the latest guidelines (please see literature review and Appendix 1 for a summary), but the reality of how anaesthetists manage PDPH may be different. The awareness of these guidelines amongst South African anaesthetists is also not known, and may be poor. There are a small number of practice-based surveys that have been published which evaluated countries including Israel, the United Stated of America, and the United Kingdom. These studies demonstrate that there is wide variation in management of PDPH (13-17). Although 85% of UK maternity units did have protocols available, many of the other countries in which surveys were performed did not have specific institutional guidelines or protocols for managing PDPH (15, 18).

There is a mass of information and a multitude of proposed methods available to treat PDPH. It is essential that PDPH is identified and managed appropriately as it is common and it is associated with morbidity, prolonged hospital stays, and increased healthcare costs (5). Anaesthetists may be overwhelmed with the knowledge and research available, and may not know what is considered best practice, especially if there are no specific guidelines available at the institutions where they are employed. According to Lavelle et al. (19), “the sheer volume of new medical knowledge makes it extremely difficult for clinicians to stay up to date and incorporate new best practices into patient care”. Well-designed clinical pathways provide benefits to both patients and providers as they can minimise unnecessary testing, decrease admission rates, reduce error and allow for shorter hospital stays (19).

Therefore, it is important to regularly assess practices of anaesthetists and create standardised processes, such as clinical pathways, to ensure delivery of a high quality of care that is evidence-based (19). There are no published surveys assessing the practices of South African anaesthetists with regards to their management of PDPH. There are no guidelines that have been endorsed by the South African Society of Anaesthesiologists.

There is also currently no recommended protocol or guideline available in the Wits Department of Anaesthesiology. Therefore, this study aims to describe the practices of anaesthetists, working in the Wits Department of Anaesthesiology, with regards to their management of PDPH. This study will determine whether management of PDPH at Wits affiliated hospitals is in accordance with the latest evidence, and OAA guidelines, and may assist with the creation and development of specific departmental guidelines.

4.2 Problem Statement

PDPH is a common complication of neuraxial anaesthesia, which is associated with poor maternal-infant bonding, increased duration of hospital stay, and increased hospital costs (5). There are numerous management options available for PDPH. International studies have demonstrated a wide variation in practice, as well as a lack of protocol/pathway-driven guidelines (11, 13-17). Guidelines have been shown to have benefits for medical providers, as well as patients (19). No such PDPH-management guidelines exist for South African anaesthetists, and there are no standardised protocols available in the Wits academic circuit for the treatment of PDPH. Surveys of practice for the management of PDPH have been performed in developed countries, and the findings of these studies have resulted in the recommendation that standardised practice guidelines be developed and implemented (11, 13-17). No South African practice surveys have been performed. It is therefore imperative that the current PDPH management practices in the Wits Department of Anaesthesiology be established, to determine the need for specific departmental guidelines/protocols.

4.3 Aim

The aim of this study is to describe the PDPH management practices of anaesthetists working in the Wits Department of Anaesthesiology.

4.4 Objectives

Primary objectives

To describe the PDPH management practices of anaesthetists working in the Wits Department of Anaesthesiology.

Secondary objectives

1. To compare the PDPH management practices of anaesthetists, working in the Wits Department of Anaesthesiology at the University of the Witwatersrand, to the current OAA guidelines.
2. To determine demographic factors that are associated with correct practice, according to the OAA guidelines.

4.5 Research assumptions

The following definitions will be used in the study.

Anaesthetist: Any qualified doctor performing anaesthesia who works in the Wits Department of Anaesthesiology including medical officers, registrars and consultants**.**

Medical officer: A qualified doctor practising in the Wits Department of Anaesthesiology under specialist supervision.

Career medical officer: A medical officer with more than 10 years of experience and is regarded as a consultant.

Registrar: A qualified doctor who is registered with the Health Professions Council of South Africa (HPCSA) as a trainee anaesthetist**.**

Junior Registrar: A registrar in their first or second year.

Senior Registrar: A registrar in their third, fourth or subsequent years.

Consultant: A qualified doctor who is registered with the HPCSA as a specialist anaesthetist capable of independent practice, or a career medical officer.

Correct Practice: A mark of 70% or more being achieved in the questionnaire, as per the modified Angoff method. The correct answer for each question would be based on the OAA guidelines. The questions included in this assessment are questions where the possible answers are covered by the OAA guidelines, namely 17, 19, 22-24, 26-33, 35-37, 39 (See Appendix 3).

4.5 Demarcation of study field

The study will be conducted in the Department of Anaesthesiology, affiliated with the Faculty of Health Sciences of the University of the Witwatersrand. The department is comprised of 214 anaesthetists: 58 consultants, 12 career medical officers, 102 registrars, and 42 medical officers (26-28).

The following hospitals are affiliated with the department:

- Charlotte Maxeke Johannesburg Academic Hospital (1200 beds)
- Chris Hani Baragwanath Academic Hospital (2888 beds)
- Helen Joseph Hospital (500 beds)
- Rahima Moosa Mother and Child Hospital (338 beds)
- Wits Donald Gordon Medical Centre (190 beds).

4.6 Ethical considerations

Approval to conduct the study will be obtained from the Human Research Ethics Committee (Medical) and the Post Graduate Studies Committee of the University of the Witwatersrand.

Permission to distribute the questionnaires will be obtained from Professor Palesa Motshabi, the Head of the Department of Anaesthesiology at Wits (Appendix 4).

A voluntary self-administered questionnaire will be utilised in this study.

The researcher will invite anaesthetists attending the departmental academic meeting to participate in the study. The study will be explained to the anaesthetists, and an information sheet (see Appendix 5) will be distributed to anaesthetists who agree to participate.

Participants will be requested to complete the survey and place completed surveys in sealed boxes that will be placed at the back of the meeting venue. Completion and return of the questionnaire will imply consent.

In the event of academic meetings being cancelled due to the COVID-19 pandemic, the questionnaires, information sheets and consent will be distributed electronically via RedCap® to staff members within the Wits Department of Anaesthesiology (29).

Questionnaires will be completed anonymously, and no identifying information will be collected on the questionnaire. Confidentiality will be ensured as only the researcher and supervisors will have access to the raw data.

The data collected will be stored securely for six years once the study is completed. The study will be conducted according to the principles of the Declaration of Helsinki and the South African Good Clinical Practice guidelines (21, 22).

4.7 Data collection

4.7.1 Research design

A prospective, descriptive, contextual, cross-sectional study will be performed using a self-administered questionnaire (Appendix 2).

A prospective study is one where the researcher plans to collect/evaluate data that is not yet in existence at the time that the research is conceived, and approval to conduct the study is sought (23). This study is prospective as the researcher has conceived the study, designed the survey, and will recruit participants, and collect the data relating to those participants thereafter.

Descriptive research is used to describe characteristics of a population or phenomenon being studied. It does not answer questions about how, when, or why the characteristics occurred (23). This study is descriptive as it will be examining the PDPH management practices of anaesthetists in the Wits department of Anaesthesiology as it currently exists.

A cross-sectional study is defined as an observational research type that analyses data of variables collected at one given point of time across a sample population. The study will include anaesthetists who attend academic meetings who consent to participate, and will therefore be cross-sectional (23).

A contextual study is one that involves specific population groups within their environment (23). This study is contextual as it will be conducted amongst anaesthetists working in the Wits Department of Anaesthesiology.

4.7.2 Study population

The study population consists of all anaesthetists working within the Wits Department of Anaesthesiology.

4.7.3 Study sample

Sample method

A convenience sampling method will be used. This method involves choosing subjects based on their availability to the researcher (23). All anaesthetists attending the academic meetings will be approached to participate in the study.

COVID amendments: All anaesthetists within the department will be invited to participate electronically using RedCap® (29).

Sample size

The sample size was determined in consultation with a biostatistician, and confirmed using Raosoft® survey sample size calculator (24). The Department of Anaesthesiology currently consists of 214 anaesthetists: 58 consultants, 12 career medical officers, 102 registrars, and 42 medical officers (26-28). An 80% response rate will be targeted, but a response rate of 66% is acceptable based on a margin of error of 5%, a confidence level of 95%, and a response distribution of 50%. Therefore, a minimum number of 138 replies would be required.

Inclusion Criteria:

- Anaesthetists working in the Wits Department of Anaesthesiology

Exclusion criteria:

- Medical interns
- Anaesthetists who do not return their survey forms
- Survey forms where only the demographic section has been completed

- **Collection of data**

Development of Questionnaire:

The questionnaire was developed following a literature review targeting the most recent evidence-based PDPH management guidelines. The questionnaire was modelled from these guidelines to assess methods of practice.

Data collected will include information about:

1) Demographics
2) The availability of guidelines
3) Practical experience and risk factors for PDPH
4) PDPH approach and conservative management
5) Epidural blood patches
6) Other modalities of treatment
7) Final care for PDPH patients

The questionnaire has been reviewed by 10 members of staff of the Wits Department of Anaesthesiology to ensure content and face validity, and feedback was be used to refine the survey.

Data Collection Process

Data will be collected at the departmental academic meetings. The researcher will approach the convenor of the meeting for permission to address the attending anaesthetists. Information about the study will be provided to the attendees of the meeting, and they will be invited to take part. The questionnaire and an information leaflet will be distributed to those who are willing to participate.

The questionnaire will take approximately 10-15 minutes to complete. Participants will be requested to place all completed questionnaires into a sealed collection box at the back of the meeting room.

In the event of academic meetings being suspended due to the COVID-19 pandemic, the questionnaires, information sheet and consent sheets will be sent out to staff members electronically. This would be done in conjunction with the use of the RedCap® platform (29).

4.8 Data analysis

Data collected from the surveys will be captured by the researcher onto a Microsoft Office Excel® spreadsheet. Data will be analysed in consultation with a statistician. Descriptive and inferential statistics will be utilised. The demographic data will be analysed using numerical and visual summaries, means, medians, standard deviations and inter-quartile ranges as appropriate.

Frequencies and percentages will be used to summarise findings relating to anaesthetic practice. Frequencies and percentages will be used to summarise the response options. Categorical data will be analysed using Chi-square and Fisher's Exact tests. Where categorical data is ordinal, a Chi-square test for trend will be used. For non-parametric continuous data, the Kruskall-Wallis and Wilcoxon summed-ranked tests will be used. A p value of less than 0.05 will be considered significant.

4.9 Significance of the study

There is no information available on the management practices of South African anaesthetists, or Wits anaesthetists with regards to management of PDPHs. PDPH is associated with increased hospital costs and morbidity (5). Practice guidelines/ protocols have been shown to have benefits for medical providers, as well as patients (19). There is currently no standardised protocol available within the Wits Department of Anaesthesiology, nor is there any South African Society of Anaesthesiologists endorsed practice guideline relating to the management of PDPHs.

Surveys of practice for the management of PDPH have been performed in high income countries, and the findings of these studies have resulted in the recommendation that standardised practice guidelines be developed and implemented (13-18). No South African practice surveys have been performed. It is therefore imperative that the management of PDPH in the Wits Department of Anaesthesiology be ascertained, to determine the need for, and motivate for, the development and implementation of department specific guidelines/protocols.

4.10 Validity and reliability of the study

Validity and reliability of the study will be ensured by

- Having a representative study sample
- Using an appropriate questionnaire based on a thorough literature review
- Having 10 specialist anaesthetists, affiliated with the Wits Department of Anaesthesiology, who have a special interest in regional and obstetric anaesthesia review the questionnaire to ensure content and face validity
- Analysing data in consultation with a biostatistician

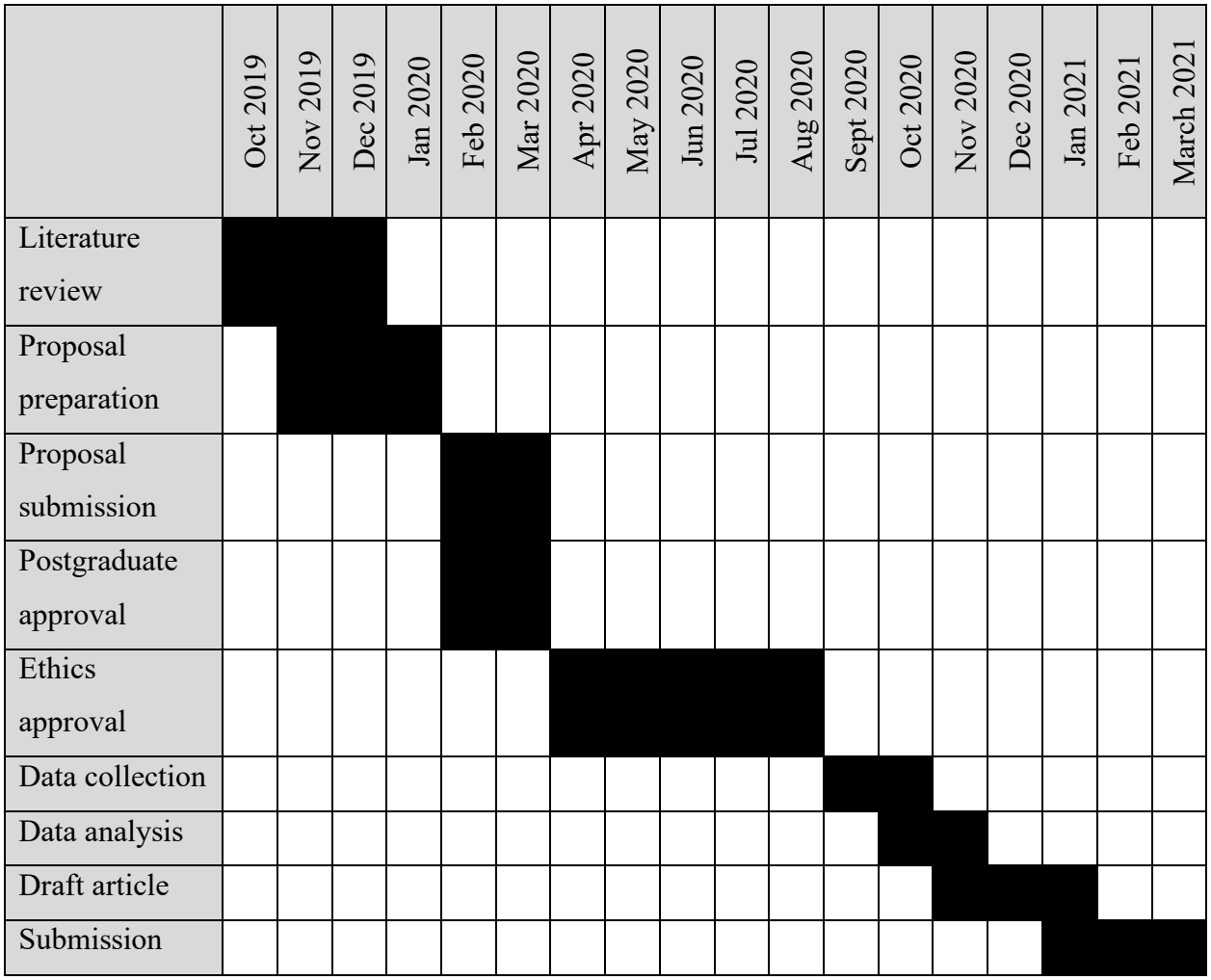
4.11 Potential limitations of the study

The study is of a contextual nature. The results will only represent the practices of anaesthetists working in the Wits Department of Anaesthesiology and therefore, the findings cannot be generalised to other departments or institutions.

The use of convenience sampling is also considered a limitation as this may result in the sampling bias.

Furthermore, participants may not respond honestly to the questions in the survey or may fail to complete the questions.

4.12 Project outline



4.13 Financial plan

Costs: Paper and Printing

Document	Price per page	Number of Pages	Number of Copies	Total
Proposal	R1	39	6	R234
Ethics	R1	40	3	R120
Questionnaire	R1	20	220	R4400
Information sheet	R1	1	220	R220
Final	R1	100	2	R200
Total				R5174

The Department of Anaesthesiology will bear the cost of printing and paper for the proposal, information leaflets, surveys, as well as documents relating to ethics and postgraduate approval.

Alternative costs in the event of the COVID-pandemic resulting in academic meetings being cancelled:

No questionnaires would be printed, as the surveys would be sent out electronically.

Document	Price	Quantity of units	Number of Copies	Total
Proposal	R1 per page	39	6	R234
Ethics	R1 per page	40	3	R120
Final	R1 per page	100	2	R200
Total				R554

The cost of the RedCap® platform is borne by the University of the Witwatersrand.

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Section 5: Appendices

Appendix 1: Summary of OAA Guidelines relating to EDBP (24)

Appendix. Guidelines on management of an epidural blood patch

Pre-epidural blood patch (EBP) procedure checklist

- Give patient written information to aid consent process (e.g. OAA headache after an epidural leaflet http://www.labourpains.com/assets/_managed/cms/files/Headache_after_epidural.pdf).
- Check when the last dose of anticoagulant was given.
- Check for evidence of maternal systemic infection.
- Check for the absence of 'red-flag' symptoms suggesting a different diagnosis e.g. change in the nature of headache, development of focal neurological signs, reduced conscious level and atypical headaches.

Consent

We recommend that written consent should be obtained and the following may be discussed:

Benefits of EBP

- Efficacy: complete relief of symptoms following a single epidural blood patch is likely to occur in up to one third of cases. Complete or partial relief may be seen in 50–80%. In cases of partial or no relief, a second epidural blood patch may be performed after consideration of other causes of headache.

Risks and side effects of EBP

- Repeat dural puncture.
- Back pain during and for several days after EBP is common and can be significant.
- Rare complications include nerve damage, bleeding and infection.

EBP procedure

- The procedure requires two clinicians. A consultant obstetric anaesthetist or experienced senior trainee should perform the epidural injection and a second clinician take blood.
- Cardiovascular monitoring and intravenous access may be considered to detect and treat bradycardia during the procedure.
- The patient may be placed in the lateral or sitting position, considering the comfort of the patient in relation to her symptoms and the preference of the anaesthetist.
- The epidural injection should be performed at the same space or one space lower than the level at which the original dural puncture occurred.
- A full aseptic technique should be employed for both the epidural component and venesection.
- The epidural space should be located before venesection is performed.
- After venesection blood should be injected immediately into the epidural space through the epidural needle. Volumes of up to 20 mL are recommended if tolerated by the patient.
- There is insufficient evidence to recommend the routine collection of blood for culture. The decision on whether to do so should remain with the individual clinician.

Post-EBP procedure management

Guidance on the management of obstetric patients immediately following an EBP is lacking. The following is suggested:

- Keep patients in the supine position for 1–2 hours.
- Regular observations of maternal pulse, blood pressure and temperature may be made following the procedure. The frequency and duration of these observations should be decided by individual units and must take into account maternal health.
- Consider prescribing laxatives to avoid constipation and advising patients to avoid twisting, bending and straining.
- Women should be reviewed by an anaesthetist within four hours of the procedure. The effect on headache and presence of side effects should be documented. After the initial review, women may mobilise and, where appropriate, they may be discharged home. Those women who remain in hospital should be reviewed daily until discharge or until symptoms resolve.
- For further review and follow-up procedures see the Appendix to part 1.

Appendix 2: Participant Questionnaire

Confidential

PDPH Survey

Dear Colleagues

My name is Kathryn Monteith and I am a registrar in the Department of Anaesthesiology at the University of the Witwatersrand. I would like to invite you to participate in my MMED research project.

My research seeks to describe how anaesthetists in the department manage postdural puncture headaches. Results of this research may assist with the establishment of departmental guidelines and protocols pertaining to the management of postdural puncture headaches.

The study has been approved by the Human Research Committee (Medical). Ethics approval number: M200603. If you have any concerns, please contact the chairperson of the committee, Professor Clement Penny, on 011 717 2301 or clement.penny@wits.ac.za. Alternatively, the secretary of the committee can be contacted on 011 717 2700 or via email at zanele.ndlovu@wits.ac.za rhulani.mukansi@wits.ac.za.

Participation in the study is voluntary and anonymous. There are no personal identifiers included within the questionnaire. Consent is implied by the completion and return of the questionnaire. All information will remain confidential and only my supervisors and myself will have access to the raw data. There is no penalty for not participating in the study.

No incentives will be provided for completing the questionnaires. The questionnaire should not take longer than 15 minutes to complete. If there are any questions prior to or during completion the survey, please feel free to ask.

Kind regards

Kathryn Monteith (Researcher), 072 473 7399

Thank you!

	Section 1 : Demographics	
1	What is your age?	◯ 25-29 ◯ 30-39 ◯ 40-49 ◯ 50-59 ◯ ≥60
2	What is your gender?	◯ Male ◯ Female
3	Years of anaesthetic experience?	◯ < 1 Year ◯ 1-2 Years ◯ 3-5 Years ◯ 6-9 Years ◯ ≥10 Years

4	What is your rank?	◯ Medical Officer ◯ Junior Registrar - 1st and 2nd year ◯ Senior Registrar - 3rd, 4th and subsequent years ◯ Consultant (This includes Career Medical Officers who have >10 Years' experience)

Section 2: Availability of Guidelines

5	Are you aware of any guidelines for the management of postdural puncture headache (PDPH)?	◯ Yes ◯ No
5a	If Yes, which guidelines?	_____
6	Does your department have official guidelines for the management of PDPH?	◯ Yes ◯ No ◯ I do not know
7	Do you think you would benefit from guidelines for the management of PDPH?	◯ Yes ◯ No
7a	If no, why? (Please specify)	_____
8	Is written information made available to the patients in your hospital with regards to the treatment options for PDPH?	◯ Yes ◯ No ◯ I do not know
9	Is there a reporting mechanism in the department for recording the number of patients treated for PDPH?	◯ Yes ◯ No ◯ I do not know

Section 3: Risk Factors

		Never	Rarely	Often	Always
10	Do you follow up your patients who receive spinal anaesthesia the day after the procedure is performed?	◯	◯	◯	◯
11	Do you follow up your patients who receive epidural anaesthesia the day after the procedure is performed?	◯	◯	◯	◯

10a	If you answered never/rarely to the follow-up of spinal anaesthesia, why?	◯ I do not have time ◯ Not concerned about PDPH ◯ Someone else will report PDPH to me ◯ Logistically not plausible ◯ Other
10b	Please specify other	_____

11a	If you answered never/rarely to the follow-up of epidural anaesthesia, why?	◯ I do not have time ◯ Not concerned about PDPH ◯ Someone else will report PDPH to me ◯ Logistically not plausible ◯ Other
11b	Please specify other	_____
12	Have you ever performed an epidural where an accidental dural puncture occurred?	◯ Yes ◯ No ◯ I have never performed an epidural
13	What would be your immediate approach to managing an accidental dural puncture?	◯ Remove needle and try at another level ◯ Feed catheter intrathecally & use in intrathecal space ◯ Abandon procedure entirely ◯ Prophylactic saline intra-epidurally ◯ Prophylactic epidural blood patch ◯ Other (please specify)
13a	Please specify other	_____
14	Do either you, or an allocated anaesthetist, follow-up patients when accidental dural puncture has occurred during the performance of an epidural?	◯ Yes ◯ No ◯ I have never performed an epidural

Section 4: PDPH Management Approach & Conservative Management

15	Have you ever been involved in the management of a patient with PDPH?	◯ Yes ◯ No
16	At the hospital where you are employed, who usually informs you/the department about a patient with suspected PDPH? (multiple options may be selected)	☐ A member of the obstetric team ☐ Ward nursing staff ☐ I find out when I follow up the patient ☐ Another anaesthetist ☐ Other (please specify)
16a	Please specify other	_____
17	What actions do you include (in your management) on the FIRST day that you see a patient with suspected PDPH? (Multiple options may be selected)	☐ History & examination ☐ Monitor and review the patient's temperature ☐ Blood tests ☐ CT scan ☐ Conservative management (IV fluids, analgesia, bed rest) ☐ Sphenopalatine ganglion block ☐ Epidural blood patch ☐ Physician/Neurology consult ☐ Other (Please specify)
17a	Please specify other	_____

18	Which of the following blood tests would you perform during the initial work-up of PDPH patients? (multiple options may be selected)	☐ I do not request blood tests ☐ FBC ☐ U & E ☐ CRP ☐ Blood Cultures ☐ Other (Please specify)
18a	Please specify other	_____

In terms of conservative management, would you prescribe any of the following?

		Yes	No
19	Oral fluids	○	○
20	IV fluids	○	○
21	Bed rest	○	○

22	What medication would you prescribe for PDPH? (multiple options may be selected)	☐ Paracetamol ☐ NSAIDs ☐ Opioids ☐ Caffeine ☐ Gabapentinoids ☐ Other (please specify)
22a	Please specify other	_____

You are half-way through the questionnaire - Thanks!

23	For the average case, how long would you trial conservative management for?	○ I don't - I immediately do an epidural blood patch/ block ○ < 24 hours ○ 24-48 hours ○ 49 -72 hours ○ >72 hours ○ Other (please specify)
23a	Please specify other	_____
24	What would your next step be, if conservative management fails?	○ Sphenopalatine Ganglion Block ○ Epidural Blood Patch ○ Greater Occipital Nerve Block ○ Epidural patch with other substances ○ Other (please specify)
24a	Please specify other	_____

	Section 5: Epidural Blood Patch (EDBP)	
25	How many epidural blood patches (EDBPs) have you done?	◯ 0 ◯ 1 ◯ 2 -5 ◯ 6 -10 ◯ 11-20 ◯ 21-30 ◯ >30
26	Which of the following complications relating to EDBP would you routinely counsel your patients on? (multiple options can be selected)	☐ Infection ☐ Repeat dural puncture ☐ Spinal haematoma ± paralysis ☐ Backache ☐ Nerve Damage ☐ Failure of EDBP ☐ Other (please specify)
26a	Please specify other	_____
27	Would you obtain written consent for the EDBP?	◯ Yes ◯ No
28	Where would you perform the EDBP?	◯ Operating theatre ◯ The ward ◯ Minor procedure room ◯ Other (please specify)
28a	Please specify other	_____
29	If you are a Registrar or an MO, would you be supervised when you perform an EDBP?	◯ Yes ◯ No ◯ Not Applicable
30	What monitors would you routinely apply when performing an EDBP? (Multiple options may be selected)	☐ ECG ☐ NIBP ☐ Pulse Oximetry ☐ Other (please specify)
30a	Please specify other	_____
31	What infection control measures would you apply when performing an EDBP? (multiple options can be selected)	☐ No personal protective equipment ☐ Mask ☐ Sterile gloves ☐ Nonsterile gloves ☐ Gown ☐ Other (please specify)
31a	Please specify other	_____

With respect to performing the EDBP:

32 Who would draw the sterile blood for the EDBP?
- ◯ Myself
- ◯ Fellow anaesthetist
- ◯ Surgeon
- ◯ Nurse
- ◯ Other (please specify)

32a Please specify other

_____

33 Approximately how many millilitres of blood would you inject for the EDBP?

_____

34 Have you ever performed a 2nd EDBP in the same patient?
- ◯ Yes
- ◯ No
- ◯ I have never performed an EDBP

35 Would you issue instructions about bed rest after an EDBP?
- ◯ Yes
- ◯ No

35a If yes, what instructions

_____

36 Would you perform an epidural patch with a substance other than blood?
- ◯ Yes
- ◯ No

36a If yes, please specify the substance/drug and the volume (in ml) you would use.

_____

Section 6: Other modalities of treatment

37 What would you use as an indication for CT brain and spinal cord imaging? (multiple options may be selected)
- ☐ Part of routine initial work-up
- ☐ Symptoms not resolving after a day of conservative management
- ☐ Symptoms not resolving after 2 days of conservative management
- ☐ Failed 1st patch
- ☐ Failed 2nd patch
- ☐ Tinnitus and/or vertigo
- ☐ Focal Signs/ Other neurological signs
- ☐ Decreased level of consciousness
- ☐ Symptoms of meningitis
- ☐ Other (please specify)

37a Please specify other

_____

38 Have you ever performed a Sphenopalatine ganglion block for treatment of PDPH?
- ◯ Yes
- ◯ No

38a If yes, how many have you performed?
- ◯ 1
- ◯ 2-5
- ◯ 6 - 10
- ◯ 11-20
- ◯ 21 - 30
- ◯ >30

	Section 7: Final Care for PDPH	
39	Are your patients who develop PDPH followed up after discharge?	◯ Yes ◯ No ◯ I do not know
39a	If Yes, where/how do they get followed up?	◯ Pain Clinic/ Anaesthetic Clinic ◯ Telephonically ◯ At the local clinic ◯ At gynaecology outpatients clinic ◯ Other (please specify)
39b	Please specify other	_____
40	Do you feel that you have sufficient knowledge and expertise to successfully manage a patient with a PDPH?	◯ Yes ◯ No

Appendix 3: Questions related to Correct Practice

The questions included in the "correct practice" component are included below. The options which are highlighted green were considered to reflect correct practice according to the OAA guidelines. Where multiple options could be selected, each was allocated one point. Options that are not specifically discussed, are incorrect or are not covered by the OAA guidelines have been removed from each question for the sake of brevity. Where there is a 'grey zone' relating to the selection of correct answers, a brief explanation follows the question. All text encased in quotations in this section is directly quoted from the OAA guidelines.

17. What actions do you include (in your management) on the **first** day that you see a patient with suspected PDPH?

	History & examination
	Conservative management (IV fluids, analgesia, bed rest)
	Epidural blood patch

In terms of conservative management:

19. Would you routinely prescribe any of the following?

Oral Fluids	Yes	
IV Fluids	Yes	No
Bed Rest	Yes	

Correct practice (CP): All 3 are correct practice, although IV fluids are only necessary to prevent dehydration if the patient cannot tolerate fluids orally. Therefore, yes or no would both be accepted as correct for the IV option.

22. What medication would you prescribe for PDPH? (Multiple options may be selected):

Tick	Drug
	Paracetamol
	NSAIDs
	Opioids
	Caffeine

CP: Opioids may be used but are advised not to be used for more than 72 hours according to the OAA.

23. For the average case, how long would you trial conservative management for? (Single best answer)

24-48 hours

*CP: For the **average** case (not severe). OAA guidelines advise reviewing after 24 hours (unless severe); the OAA guidelines also advise to avoid doing an EDBP with less than 48 hours as there is an increased need for repeat patch.*

24. What would your next step be, if conservative management fails? (Single best answer)

Epidural Blood Patch

26. Which of the following complications relating to EDBP would you routinely counsel your patients on? (multiple options can be selected)

	Infection
	Repeat dural puncture
	Spinal haematoma ± paralysis
	Backache
	Nerve Damage
	Failure of EDBP

27. Would you obtain written consent for the EDBP?

Yes

CP: "Written consent should be obtained"

28. Where would you perform the EDBP? (Single best answer)

Operating theatre	Minor procedure room

CP: Guidelines don't specify a site, but state that it requires monitoring and full aseptic technique, therefore either theatre or a minor procedure room would cover this and be accepted.

29. If you are a Registrar or an MO, would you be supervised when you perform an EDBP?

Yes

CP: "Senior anaesthetists must be involved in the management of PDPH"

"A consultant obstetric anaesthetist or experienced senior trainee should perform the epidural injection and a second clinician to take blood"

30. What monitors would you routinely apply when performing an EDBP? (Multiple options may be selected)

	ECG
	NIBP
	Pulse Oximetry

CP: "Cardiovascular monitoring and intravenous access may be considered to detect and treat bradycardia during the procedure"

31. What infection control measures would you apply when performing an EDBP? (multiple options can be selected)

	Mask
	Sterile gloves
	Gown

CP : "full aseptic technique should be employed for both the epidural component and venesection."

With respect to performing the EDBP:

32. Who would draw the sterile blood for the EDBP? (Single best answer)

Fellow anaesthetist	Surgeon	Nurse	Other (please specify): _____

CP: "Other clinician"

33. Approximately how many millilitres of blood would you inject for the EDBP?

10-20mls

CP: "Volumes of up to 20 mL are recommended if tolerated by the patient", "stop before 20 mL is injected if not tolerated by the patient"

35. Would you issue instructions about bed rest after an EDBP?

Yes

35a. If yes, what instructions:

Supine 1-2 hours

CP: Supine for 1-2 hours advised by OAA

36. Would you perform an epidural patch with a substance other than blood?

No

37. What would you use as an indication for CT brain and spinal cord imaging? (multiple options may be selected)

	Failed 2nd patch
	Tinnitus and/or vertigo
	Focal Signs/ Other neurological signs
	Decreased level of consciousness

CP: "the diagnosis of obstetric post-dural puncture headache is strongly suspected, there is no evidence that imaging is needed before performing an epidural blood patch."

39. Are your patients who develop PDPH followed up after discharge?

Yes

Total = 37 Points

Appendix 4: Letter of Permission for Professor Motshabi

Dear Prof Motshabi

My name is Kathryn Monteith. I am one of the registrars in Department of Anaesthesiology. I am planning to do my MMed research, titled "a survey of postdural puncture headache management practices within an academic department". Please may I have your permission to distribute a questionnaire to the members of the department. I would be requesting completion of a survey by medical officers, registrars and consultants. I would like to distribute the questionnaires at the academic meetings.

Participation in the study is voluntary and anonymous. Consent will be implied by the completion and return of the questionnaire. Information will remain confidential and only my supervisors and myself will have access to the raw data.

The aim of the study is to describe the postdural puncture headache management practices of Wits anaesthetists. I will evaluate the results to determine if practice is standardised, and in line with the current literature and available guidelines. I may also make recommendations with respect to the development and distribution of department guidelines/protocols.

Yours Sincerely
Kathryn Monteith
0724737399
Kmm.monteith@gmail.com

Appendix 5: Information Sheet for Colleagues

Dear Colleagues

My name is Kathryn Monteith and I am a registrar in the Department of Anaesthesiology at the University of the Witwatersrand. I would like to invite you to participate in my MMED research project.

My research seeks to describe how anaesthetists in the department manage postdural puncture headaches. Results of this research may assist with the establishment of departmental guidelines and protocols pertaining to the management of postdural puncture headaches.

The study has been approved by the Human Research Committee (Medical). Ethics approval number: M200603. If you have any concerns, please contact the chairperson of the committee, Professor Clement Penny, on 011 717 2301 or clement.penny@wits.ac.za. Alternatively, the secretary of the committee can be contacted on 011 717 2700 or via email at zanele.ndlovu@wits.ac.za rhulani.mukansi@wits.ac.za.

Participation in the study is voluntary and anonymous. There are no personal identifiers included within the questionnaire. Consent is implied by the completion and return of the questionnaire. All information will remain confidential and only my supervisors and myself will have access to the raw data. There is no penalty for not participating in the study.

No incentives will be provided for completing the questionnaires. The questionnaire should not take longer than 15 minutes to complete. All questionnaires, whether completed or not, should please be returned and placed in the appropriately labelled box. If there are any questions prior to or during completion the survey, please feel free to ask.

Kind regards

Kathryn Monteith (Researcher), 072 473 7399

Appendix 6: Human research ethics committee clearance certificate

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Dr K Monteith

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M200603

NAME: (Principal Investigator)	Dr K Monteith
DEPARTMENT:	School of Clinical Medicine Department of Anaesthesiology Medical School University
PROJECT TITLE:	A survey of postdural puncture headache management practices within an academic department
DATE CONSIDERED:	2020/06/26
DECISION:	Approved conditionally
CONDITIONS:	Approval of the Registrar is required before approaching staff and students to participate in a research project - Nicoleen.Potgieter@wits.ac.za
SUPERVISOR:	Drs J Wagner and Dr J Herbst
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	2020/08/07

This clearance certificate is valid for 5 years from the date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the 3rd Floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.
I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to submit details to the Committee. **I agree to submit a yearly progress report**. When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in **June** and will therefore reports and re-certification will be due early in the month of **June** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

2020/08/15
Date

Appendix 7: Permission letter from the Anaesthesiology Head of Department

WITS UNIVERSITY

Department of Anaesthesiology
University of the Witwatersrand

Tel: 011 488 4344/ Fax: 011 488 4343
Private Bag X39, Parktown 2193

FACULTY OF HEALTH SCIENCES

24 August 2020

Dr Kathryn Monteith
Registrar
Department of Anaesthesia
University of the Witwatersrand

Dear Dr Monteith

RE: PERMISSION TO CONDUCT A SURVEY

Permission is hereby granted to conduct a survey for your MMed study, titled: *"A survey of postdural puncture headache management practices within an academic department"*. This survey will be conducted at the Wits Anaesthesia training sites according to the set inclusion/exclusion criteria. The study is also subject to prior ethics clearance.

Yours sincerely,

Prof Eddie Oosthuizen
For Dr P Motshabi: Academic Head

Appendix 8: Graduate studies approval

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

OFFICE OF THE DEPUTY REGISTRAR

26 October 2020

Kathryn Monteith
Staff number (A0032180)
MMED
School of Anaesthesiology

TO WHOM IT MAY CONCERN

"A survey of postdural puncture headache management practices within an academic department"

This letter serves to confirm that the above project has received permission to be conducted on University premises, and/or involving staff and/or students of the University as research participants. In undertaking this research, you agree to abide by all University regulations for conducting research on campus and to respect participants' rights to withdraw from participation at any time.

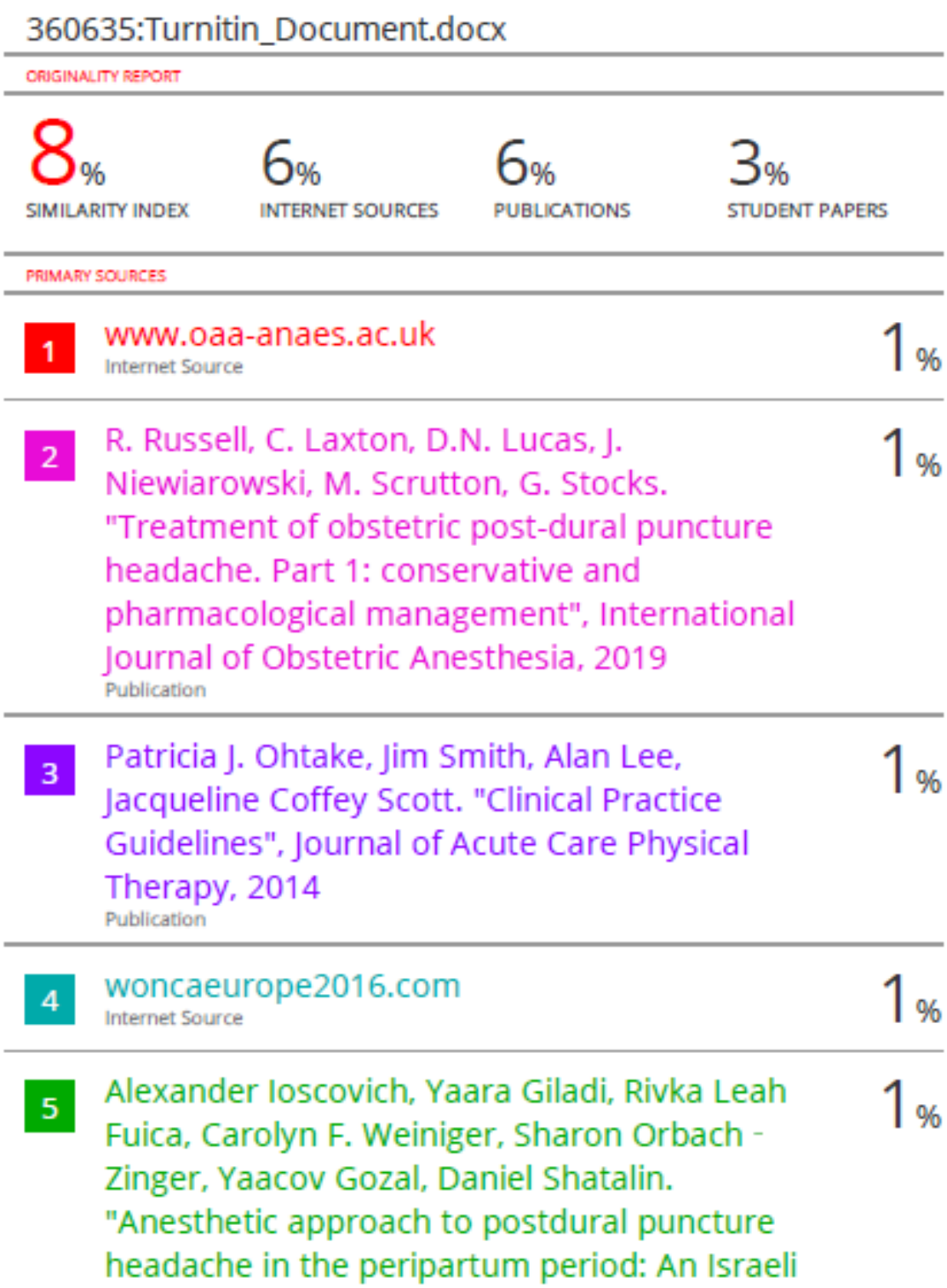
If you are conducting research on certain student cohorts, year groups or courses within specific Schools and within the teaching term, permission must be sought from Heads of School or individual academics.

Ethical clearance has been obtained. (Protocol number: **M200603**)

Research Commencement: (As per HOD consent)

Nicoleen Potgieter
University Deputy Registrar

Appendix 9: Turnitin Report



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