Iliac Crest Donor Site Morbidity in Patients undergoing Anterior Cervical Discectomy and Fusion at Charlotte Maxeke Johannesburg Academic Hospital

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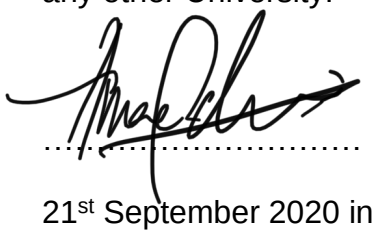
A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, in partial fulfilment of the requirements for the degree of Master of Medicine

Johannesburg, 2020

DECLARATION

I, Ikechukwu Amaechi Egbunike, declare that this Research Report is my own unaided work. It is being submitted for the Degree of Master of Medicine in the branch of Orthopaedic Surgery at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.



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21st September 2020 in Johannesburg

DEDICATION

This report is dedicated to my parents, Prof. Gabriel Nwachukwu Egbunike and Mrs. Nkechi Akuzie Egbunike, who laid a solid foundation upon which to build, and my wife, Chizgani & kids Zikora, Wezi, Kene and Kodi who bring Joy and Fullness to my life.

ABSTRACT

Background: Iliac Crest Bone Graft is the gold standard for grafts used in spine surgery. Despite this, there is a decline in its use in Anterior Cervical Discectomy and Fusion (ACDF). This is mainly due to the perceived donor site morbidity associated with its harvesting. The aim of this study was to evaluate iliac crest donor site morbidity in patients undergoing ACDF at a tertiary hospital's orthopaedic department. The objectives were to (i) determine the incidence of donor site morbidity in these patients, (ii) analyse demographic data pertaining to age and gender, as well as (iii) determine the severity of each adverse effect.

Methodology: This was a retrospective study with a prospective recall. Patients who met the inclusion criteria were followed up at the spine unit out-patients department where the study was explained to them and a questionnaire was given to them for completion, after signing an informed consent form. The data were statistically analysed using the IBM SPSS 25 ® software.

Results: There were 22 patients who met the study inclusion criteria. Data were stratified into categories.

Discussion: None of the study participants experienced any major donor site morbidities, and most of the minor donor site morbidities were self-limiting and resolved timeously. The study compared remarkably well with similar studies done around the world.

Conclusion: The study demonstrates that Iliac Crest Bone Graft is a cost effective, safe procedure to do, can be done with maximum patient satisfaction and has minimum significant morbidity to the patient.

ACKNOWLEDGEMENTS

I would like to thank my supervisor, Dr S.A. Khan, for his guidance through the journey of this research study and his mentorship. Special thanks to Dr Brenda Milner and Dr Maxwell Jingo for their advice and support. Great thanks to Mr Ajidahun for his input on my data analysis.

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NOMENCLATURE

ABG: Autologous Bone Graft

ACDF: Anterior Cervical Discectomy and Fusion

ASIS: Anterior Superior Iliac Spine

BMI: Body Mass Index

BMP: Bone Morphogenic Protein

Cm: centimetres

CMJAH: Charlotte Maxeke Johannesburg Academic Hospital

DSM: Donor Site Morbidity

ICBG: Iliac Crest Bone Graft

LFCN: Lateral Femoral Cutaneous Nerve

Mm: millimetres

MVA: Motor Vehicle Accident

PEEK: Polyethereetherketone

TGF-β: Transforming Growth Factor Beta

VAS: Visual Analogue Scale

1. CHAPTER ONE – INTRODUCTION AND LITERATURE REVIEW

1.1 Background and literature review

Anterior Cervical Discectomy and Fusion (ACDF) is a surgical procedure done in the neck to alleviate the symptoms of cervical spondylosis and instability (1). The intervertebral disc space is replaced with material that will restore the original disc height as well as promote fusion (1). Due to prolonged surgical time and cost implications, many spine surgeons opt to use synthetic cages made from various material (2). These materials used include polyetheretherketone (PEEK) cages (a non-absorbable biopolymer), Tantalum cages as well as Allograft (cadaveric bone from a tissue bank) (3). An anterior plate may then be used to buttress the substitute material in the disc space. This increases the fusion rate for single level procedures to 92 - 100% (4).

Though these other materials can be used, Autologous Bone Graft (ABG) is considered the gold standard for grafting (1,2,3,5,6,8) and possesses the three desirable properties of any graft material: it has osteogenic, osteoconductive and osteo-inductive properties (2,7,8), with the iliac crest being the most common donor site in the body (9), due to its easy accessibility and abundance of bone (1,9). The graft can either be taken from the anterior or the posterior iliac crest, with the posterior site yielding more bone with less morbidity (1). Despite this, the anterior iliac crest is more often used when doing anterior neck fusions, as the patient is lying supine and this allows for simultaneous harvesting and recipient site preparation (1).

Other donor sites for ABG include the ribs, femur and the tibia, with pleural tears and post-operative tibia fractures being possible adverse sequelae in these instances (10). ABG also has the advantages of being an excellent structural support, with minimal risk of disease transmission, and lack of immunogenicity (1,2,11). Harvested bone contains osteoblasts, Bone Morphogenic Proteins (BMPs), Transforming Growth Factor Beta (TGF-β), as well as a ready bony matrix, with the

cancellous bone containing readily available channels for vascularisation (11). A disadvantage of ABG is that of relatively short supply as the host is still alive. It also usually entails an additional surgical site, and the phenomenon of Donor Site Morbidity (DSM). According to Maben (2018), DSM refers to complications and functional restrictions that a patient undergoes because of harvesting a graft from a donor site, or any event that required a modification of the post-operative management (12).

Bone grafting is a common operative procedure, with as many as 200,000 (9) to 500,000 (3) bone grafting procedures performed in the United States every year, and more than one million worldwide in 2001 (3). The first mention of a bone transplant was in Church literature in 1682, while Macewen in 1878 performed the first successful bone transplant using an aseptic technique (13). The procedure involves taking a piece of bone from one part of the body, called the donor site, and inserting it into a bony defect elsewhere in the body, called the recipient site, to provide support, fill voids and promote healing in that area (7). These recipient sites include the vertebral column (1,2), maxillofacial bones (5), as well as carpal bones for scaphoid non-unions (9), to name a few.

There are various disparities in the literature: The overall DSM rate in 81 studies was just under 20%. These studies had a total of 6499 patients and 1249 donor sites/complications (10). In a prospective study, the DSM rate when using anterior iliac spine in the paediatric population was 2.94%, while another retrospective review showed a rate of 24.00% when using the posterior iliac spine (7). Swan *et al*. (10) in a study looking at ICBG morbidity in patients undergoing bone grafting of the cleft alveolus, found only 12.50% of their patients experienced DSM, with pain being the most common complication - Palmer *et al*. reporting it as 6.16%, Schwartz *et al*. 19.00% and Schaaf *et al*. 4.00% (1), respectively, with the study by Jafari *et al*. (1) showing women experience more pain than men.

Qi *et al*. (14), in a prospective study published in 2015, examined iliac donor site pain and regeneration, with a 10-year follow-up. They found that the pain was significantly less three years post-operative, as compared to one-year post-operative (14). They also observed the phenomenon of bone regeneration in the

ilium, but they were unfortunately unable to correlate this regeneration with a decrease in pain due to their small sample size. DSM includes acute and chronic pain, gait disorders, stress fractures, itching, haematoma, blood loss, deformity perforation of the peritoneum, hernias, hip fractures (1,7,8), superior gluteal artery injury, and enterocutaneous fistula (13). These morbidities can be grouped into major and minor categories (3), according to Younger and Chapman (18):

I. **Minor DSMs** are self-limited events that do not require an additional surgical procedure and are therefore managed non-operatively. They occur more frequently than major morbidities, with an incidence of 46% (6).
II. **Major DSMs** have an incidence of 26% (6) and are those complications that require additional surgery and lead to prolonged hospitalisation.

Some of the morbidities include:

Pain: This is the most frequent complaint (6), and could either be acute or chronic. This is usually experienced at the donor site and can sometimes in the early post-operative stages, be more than the main operation site (2). Spontaneous chronic pain at the donor site can be as high as 28 - 31%, with an average of 3.8 on the Visual Analogue Scale (VAS). The cause of the chronic pain is thought to be associated with muscle mobilisation, destruction of the external cortex of the iliac wing, and nerve damage with subsequent neuroma formation (2,6).

Gait Disturbance: This has been reported in many studies. In a study by Matsa *et al*., 28% of patients suffered from gait disturbance in the first month post-operatively before returning to their normal gait pattern, while other studies have been as low as 6%. In another study by Cansiz *et al*., the authors showed a full recovery of pre-operative gait at three weeks post-surgery. (15)

Neurological changes: This is due to injury of the lateral femoral cutaneous nerve (LFCN), a sensory branch originating from the posterior roots of L2 and L3.

This nerve runs an aberrant course over the iliac crest in about 9.9% of the population, (7,13) making them vulnerable to injury during graft harvesting. The

incidence of LFCN injury is between 2 - 31%, and symptoms range from numbness, tingling, burning or pain over the anterolateral aspect of the thigh (7).

Infection: Arrington *et al*. reported incidences of 1.2% and 1.7% for superficial and deep infections, respectively (13). Infection may be due to the subcutaneous nature of the area, as well as the proximity to the gut.

Iliac Crest Fractures: A rare complication, approximately 50 cases have been reported in the literature. They occur when a graft is taken from the anterior iliac crest, with the mechanism of fracture related to the attachment of muscles in the area Sartorius and Tensor Fascia Lata muscles pull downwards on the iliac spine. Techniques to reduce the risk of fractures include harvesting less than 30 mm of bone and the graft site being more than 23 mm from the Anterior Superior Iliac Spine (ASIS) (8).

1.2 Surgical Anatomy and Procedure

The iliac bone (see Figure 1.1) is the upper wing-like part of the pelvic girdle. It is the widest part of the girdle and acts as a form of attachment to muscles of the gluteal region, as well as the thigh. It also acts as a form of protection for the pelvic organs. It attaches to the sacral part of the spine posteriorly and together with the ischium and pubis, forms the hip bone which contains the acetabulum for articulation with the femoral head.

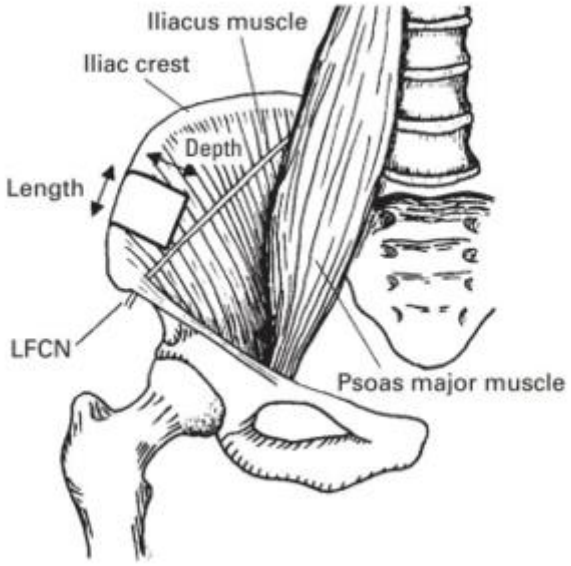

Figure 1.1: Anatomy of the Iliac Bone (12)

These complications may be dependent on the surgical incision and the amount of harvested graft (1), therefore, various graft techniques have been developed to try to minimise adverse sequelae at the donor site (3,13). These can be divided into four broad categories (3):

1. **Trapdoor techniques:** a bone flap is made in the iliac crest and subcortical bone is removed, after which the flap is replaced.
2. **Splitting techniques:** involves a vertical force to create a split or fissure in the iliac crest, e.g. Wolfe-Kawamoto technique.
3. **Window techniques:** a bony segment that includes the cortex is removed from the iliac crest. This is usually sub-crestal thereby making a “window”.
4. **Trephine extraction:** minimally invasive. A trephine needle or bone grinder is used to fill a trephine tube.

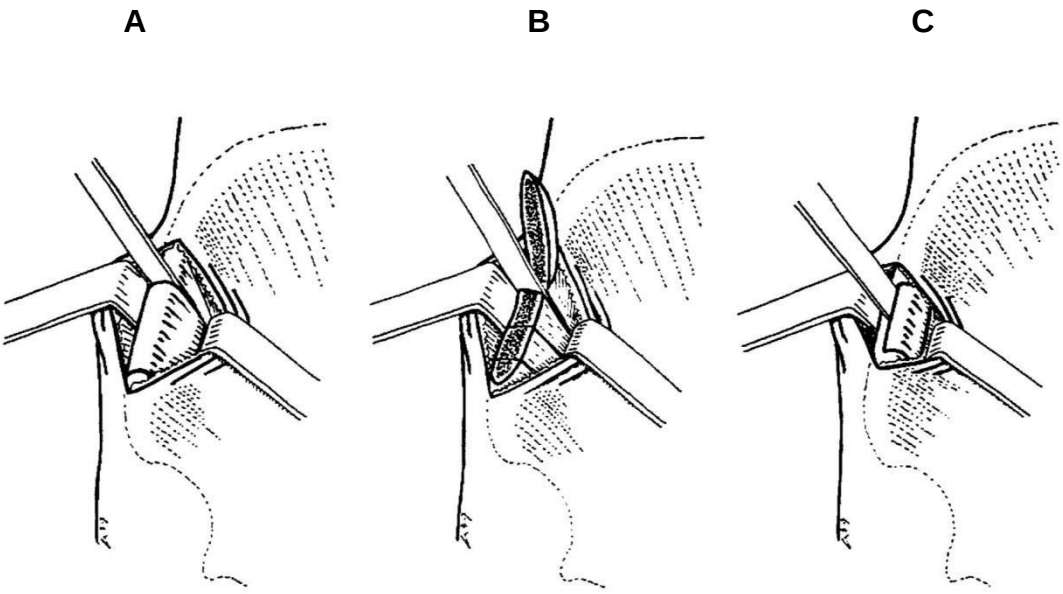

Figure 1.2: Methods of Harvesting ICBG (12)

A: Removal of tricortical graft, including iliac crest

B: Removal of bi-cortical graft preserving the iliac crest

C: Removal of graft involving only the inner table of the iliac crest

When harvesting from the anterior iliac spine, using any of the above techniques, the patient is placed supine, with a bolster under the ipsilateral gluteal area, making it more accessible (11). This area is then sterilised and draped at the same time as the recipient site (the neck). A longitudinal surgical incision reduces the amount of fibrous tissue formation. One such incision is made parallel to the iliac crest, 2 cm posterolateral to the anterior ASIS. Skin is pulled proximally before the incising, thereby leaving the final scar off the bony prominence. This incision is deepened through the deep fascia, which is incised as a flap to reach the iliac crest periosteum. For cancellous bone retrieval, a trapdoor can be raised, cancellous bone curetted out, and the trapdoor closed.

To obtain a tricortical bone graft, which is the type of graft we use at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), subperiosteal stripping of muscle off both the inner and outer tables of the ilium is done. The length and width

of the graft required is measured with a calliper and excised using an oscillating saw initially, then an osteotome for final break-off. The harvest site must be two fingerbreadths posterior to the ASIS, thereby reducing the risk of fractures (due to the downward pull of the rectus femoris and sartorius muscles). Bone wax is used to achieve haemostasis, after which the overlying fascia and skin is repaired. Drains are not routinely inserted.

Tanishima *et al*. (16) recommended smoothening of the sharp edges at the harvest site, while reconstruction of the graft site with resorbable mesh has also been shown to reduce early post-operative pain (14). Blumenthal *et al*. also showed that a continuous application of 0.2% ropivacaine through an iliac crest catheter after iliac bone grafting offered satisfactory pain relief for the first 48 hours, and the benefits were still present after three months (17). Most of the studies done to date indicate a significant incidence of DSM from ICBG harvesting however, the incidence at CMJAH is unknown. Therefore, the purpose of the proposed study was to determine the incidence of DSM in patients who underwent ICBG harvesting for ACDF.

1.3 Problem Statement

In South Africa, 84% of the population depend on the public sector for health services and ICBG being the gold standard for bone grafting is a rare case of the “cheaper” option being the better option with the only limiting factor being the perceived DSM.

1.4 Study Justification

There are no academic studies regarding the incidence and severity of ICBG DSM in the local population of South Africa. This study looked into the significance of this perceived DSM, in a bid to reduce the spending costs in the public Health Sector.

1.5 Study Aim and Objectives

The aim of the study was to determine the incidence of post-operative morbidity experienced by patients with degenerative spine disease as well as traumatic spine injuries undergoing ICBG for ACDF at CMJAH.

The specific objectives included:

- To analyse demographic data pertaining to age, gender and Body Mass Index (BMI).
- To determine which adverse effects occur and their severity thereof, post ICBG in patients undergoing ACDF.

2 CHAPTER 2 - METHODOLOGY

2.1 Study Design

This was a retrospective study with a prospective recall

2.2 Study Site

The study took place at the Orthopaedic Surgery Department at CMJAH.

2.3 Study Population

The study population consisted of patients at CMJAH who underwent ICBG during an ACDF procedure within the nine years, i.e. 1st January 2010 until 31st December 2018. All patients recruited were adults of the age of 18 and older.

2.4 Method and Selection Criteria

All Patients who underwent an ACDF with bone graft within the time frame specified were identified from the operating theatre logbook. Their contact details (phone numbers) were then obtained from the hospital admission clerk's office. These patients were then contacted telephonically to find out their next spine clinic appointment date, at which point they were seen by the principal investigator, consent was obtained to participate in the study, and a questionnaire was given to them to complete. A translator was used for those patients who were more comfortable in another language other than English.

Inclusion criteria:

- Patients 18 years of age and older, at the time of the operation
- Individuals with degenerative and traumatic cervical spine disease.
- All genders
- Patients undergoing one level fusion per sitting
- Patients in whom ABG was taken from the iliac crest

Exclusion criteria:

- Patients undergoing multiple grafts from the same site

- Patients that have undergone pelvic or hip orthopaedic surgery
- Patients participating in other studies
- Patients with neurologic fall-out post trauma, i.e. Paraplegic/Quadriplegic patients

2.5 Data collection

Data collection began after permission and ethical clearance were obtained. Data were collected from hospital theatre records, as well as questionnaires given to the patients. A Microsoft excel sheet was created with the patient's study number, age and all other relevant parameters.

2.6 Ethics

An ethical clearance certificate was obtained. (see Appendix B). Permission from the hospital CEO to conduct research was granted (see Appendix A). The Human Research Ethics Committee (HREC) (Medical), University of the Witwatersrand clearance was obtained (Certificate no: **M1911139**, Appendix B). Patient confidentiality was maintained during the data collection process. The data collection sheet did not contain any patient names or hospital numbers and only study numbers were used (see Appendix C).

2.7 Data Analysis

Data were exported into a Statistical Package for the Social Sciences (IBM SPSS 25 ®). Descriptive statistics of percentages and frequency were used to summarise the categorical data. Depending on the normality of the data set, the mean and standard deviation or median and interquartile range were used to summarise the continuous data.

3 CHAPTER THREE - RESULTS

3.1 Demographic characteristics

A total of 22 patients who had iliac crest surgery between 2010 and 2018 at CMJAH participated in the study, the average age of the patients was 40.95 (SD = 11.59) years (see Table 3.1) and the majority (81.82%, n = 18) were males (see Figure 3.1).

Table 3.1: Demographic characteristics

Demographics	Mean (SD)
Age in years	40.95 (11.59)
Weight in kg	72.5 (10.96)
Height in meters	1.74 (0.09)

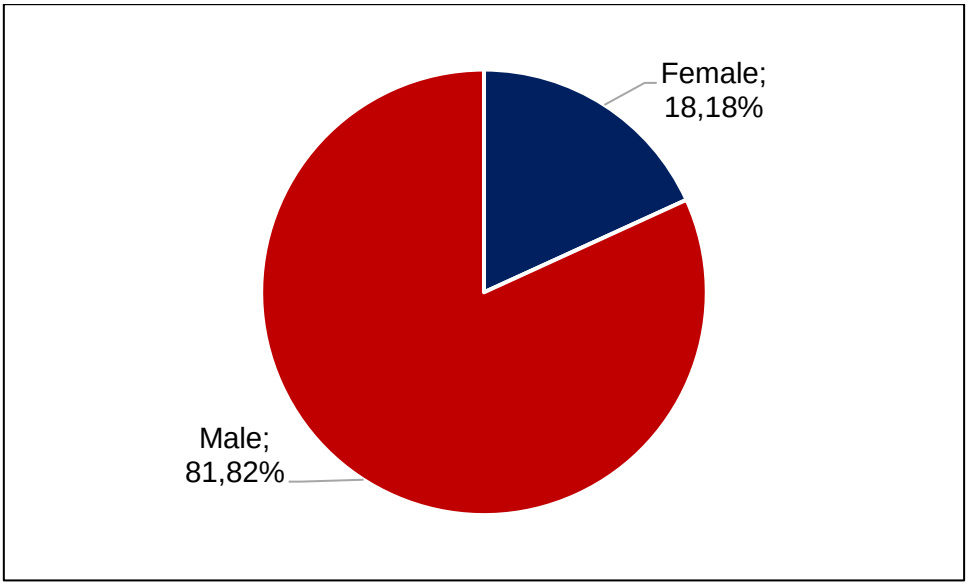

Figure 3.1: Gender distribution of the patients (n = 22)

3.2 Diagnosis of the patients

The majority of the patients were diagnosed with degenerative spine disease (59.09%) as shown in Table 3.2.

Table 3.2: Diagnosis of the patients

Diagnosis	n	%
Degenerative spine disease	13	59.09
Trauma	9	40.91

3.3 Site of graft

In the majority (63.64%) of the patients, the graft was taken from the left front and 90.91% reported infection at the site of graft as outlined in Table 3.3.

Table 3.3: Side of graft

Which side was the graft taken from?	N	%
Left anterior	14	63.64
Right anterior	7	31.82
Left posterior	1	4.55
Right posterior	0	0.00
Any infection at the IBG site?		
Yes	1	4.55
No	21	95.45

3.4 Pain

As shown in Figure 3.2, 83.36% of the patients reported pain at donor site post-operatively. The mean VAS (SD) was found to be 4.22 (2.62).

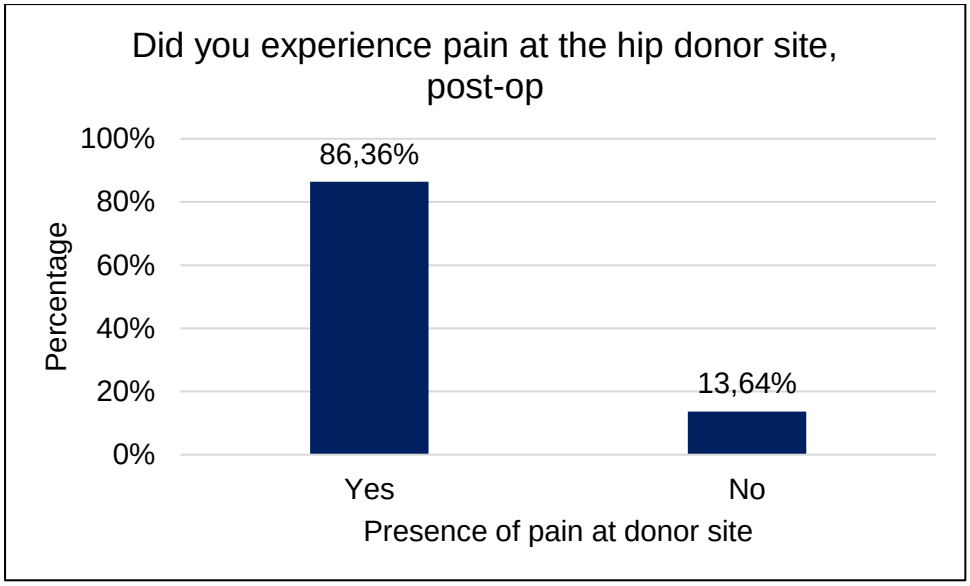

Figure 3.2: Presence of pain at donor site (n = 22)

As outlined in Table 3.4, the majority of the patients with pain (57.89%) reported that the pain lasted for one week to one month, and only two patients reported pain that lasted for more than five years.

Table 3.4: Duration of pain at donor site

How long did the pain at the donor site last?	n	%
1 week – 1 month	11	57.89
1 month – 6 months	2	10.53
6 months – 1 year	3	15.79
1 year – 5 years	1	5.26
> 5 years	2	10.53

3.5 Numbness

Post-operatively, 45.45% of the patients reported numbness at the donor site as shown in Figure 3.3. The median duration of numbness was six months (6 – 12 months).

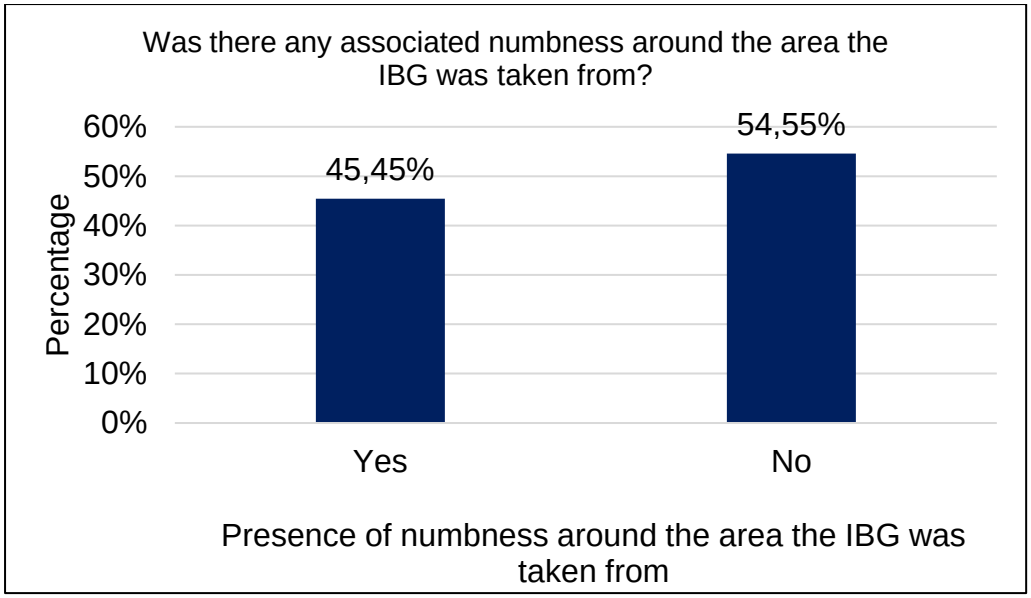

Figure 3.3: Presence of numbness at donor site (n = 22)

3.6 Itching

Post-operatively, 45.45% (n = 10) of the patients reported itching at the donor site as shown in Figure 3.4. The median duration of the itching was one month (1 – 2 month).

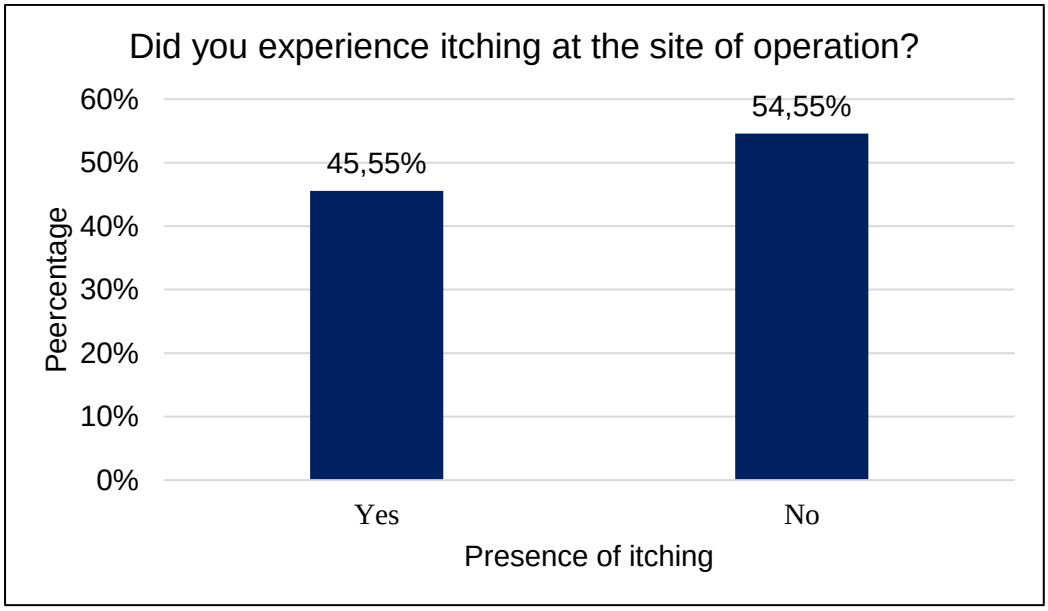

Figure 3.4: Presence of itching at donor site (n = 22)

3.7 Defect felt through the skin

Only 22.73% of the patients reported that the defect could be felt through the skin as shown in Figure 3.5. The median duration of the defect feeling was 12 months (12 – 18 months).

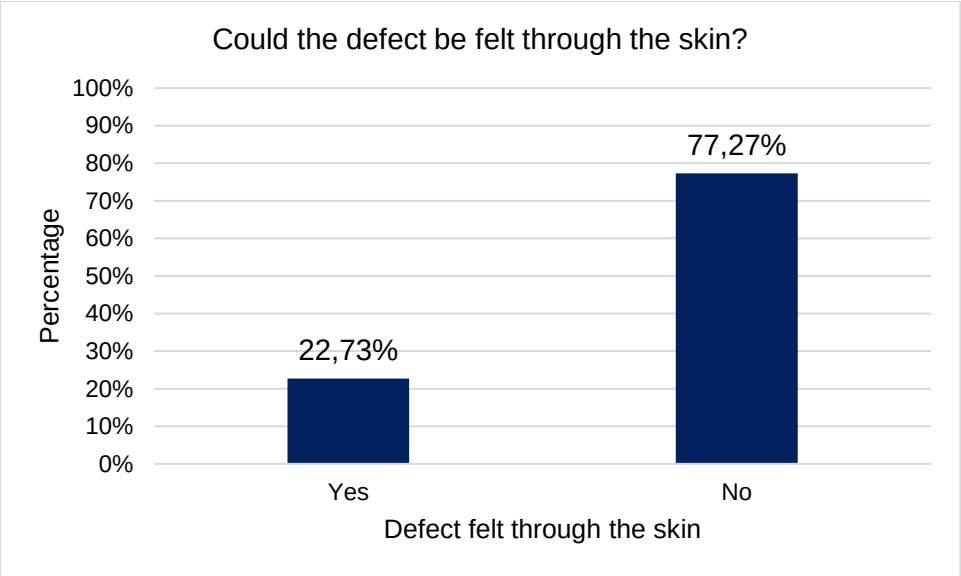

Figure 3.5: Defect be felt through the skin (n = 22)

3.8 Ambulation

Post-operatively, only 40.91% (n = 9) of the patients had problems with walking post bone graft. The majority of the patients (76.19%, n = 16) did not require a walking aid post-operatively as outlined in Table 3.5. The median duration of using the walking aid was four months (3 – 12 months).

Table 3.5: Walking post-operatively

Did you have problems walking post bone graft?	n	%
Yes	9	40.91
No	13	59.09

Was a walking aid (crutches, walking frame, wheel chair) needed post op?		
Yes	5	23.81
No	16	76.19

3.9 Patient satisfaction

Generally, the majority of the patients were satisfied with the outcome of the procedure (90.91%), Most of them were also satisfied with the scar (95.45%) and would recommend the procedure to a friend (90.91%) as outlined in Table 3.6.

Table 3.6: Patient satisfaction with the procedure

Patient satisfaction with the procedure	n	%
Are you satisfied with the outcome of the operation?		
Yes	20	90.91
No	2	9.09
Are you satisfied with the scar?		
Yes	21	95.45
No	1	4.55
Would you recommend the procedure to a friend?		
Yes	20	90.91
No	2	9.09

4 CHAPTER - DISCUSSION

4.1 Discussion

This study was undertaken to determine the incidence and degree of morbidity encountered by patients who had iliac crest bone graft harvesting while undergoing ACDF at a tertiary health institution in South Africa. These morbidities can be classified as either major or minor. Major morbidities/complications are rare, and include arterial injury, peritoneal perforation, pelvic fractures, and hernias through the donor site (19,20,21). Minor morbidities include stress fractures (22), gait disturbance (10,23,24), superficial infections (10,19,25), paraesthesia (22,23,26), poor cosmesis (23,26,27), haematomas, and acute and chronic donor site pain (22,23,24,25,26,27). The mean age in the study was 40.95 +/- 11.59 (see Table 3.1), with 81.8% of the participants being male (see Figure 3.1). The reason there were more males in the study may be due to the fact that cervical spondylosis is more common in men, as well as men being more susceptible to risky behaviour leading to motor vehicle accidents (MVAs) and other traumatic incidents (28,29,30). Of these patients, 59% were operated on due to degenerative disease of the cervical spine and 41% due to an acute traumatic injury to the cervical spine. All the patients had ICBG harvested for their ACDF procedure.

In our spine unit, to save time, the harvesting of the ICBG is done by the assistant while the Smith Robinson anterior neck approach is done by the main surgeon. The neck approach, in our unit, is usually done from the right side of the patient. Due to this, over 60% of the grafts taken in our study were from the left anterior iliac crest (see Table 3.3). This time saving simultaneous approach to ICBG harvesting and ACDF was also used by Pollock *et al*. (1). Only one patient (5%) in our study developed wound sepsis (partial wound breakdown), which resolved after treatment with antibiotics and daily dressings for five days. Pain at the ICBG site was reported by 86% of the study participants (see Figure 3.2). Of these patients, only 42% reported the pain lasting more than one month. About 16% had their pain lasting six months to a year, and 5.26% lasting between one and five years (see Table 3.4). The long standing pain in 5.26% of our participants correlates favourably with the

study by Schaaf *et al.* who reported chronic donor site pain in 4.00% of their patients (31)

Using the VAS, Reuben *et al*. (32) reported the degree of donor site pain to be 4.8 on day one post-operatively and 3.5 on the post-operative day five. The average pain at the ICBG site in our study post-operative was 4 out of 10. Ironically, the only participant in our series to sustain an avulsion fracture to the anterior superior iliac spine post ICBG harvest had pain lasting three months only.

Though Swartz *et al*. (33) reported numbness existing in 24% of their patients; we report localised numbness at the site of the graft from 45.45% of the participants (see Figure 3.3) with a mean duration of six months. None of the patients reported a wide area of numbness radiating down the lateral aspect of the thigh which would have signified lateral cutaneous nerve damage (1). Localised itching was experienced by 45.55% of the patients, most of whom stopped feeling it after one month. This corresponds with the time of healing of the wound. This contrasts with Jafari *et al*. (9) and Palmer *et al*. (6), studies who reported a rate of 1.63% and 3.3%, respectively. Twenty-two percent (22%) of the patients said that they felt the defect in the iliac crest made after the ICBG was taken. Most of these patients were those were done before the spine unit adoption of the trapdoor technique of harvesting. About 41% of the patients experienced a limp while ambulating post ICBG. The mean duration for the limp was four months. Overall, 90% of our patents were satisfied with the ICBG procedure, while 95% were satisfied with the scar. All but one of the participants indicated that they would recommend the procedure to a friend. From our study, 4.55% of our participants were not satisfied with their scar. This is in keeping with studies by Jafari, Palmer and Schwartz (3.27%, 3% and 5%, respectively) (9,6,31).

Table 4.1: Comparing post-op morbidity pain, ambulation, paraesthesia and satisfaction index with the similar study done by Pollock *et al*.

Question	Our study	Pollock *et al*. (1)
	% (n = 22)	**%** (n = 24)
Experienced pain at donor site	**83.36** (19)	**91.3** (21)
Problems with ambulation	**40.9** (9)	**54.6** (12)
Walking aid post op	**23.8** (5)	**19.1** (4)
Paraesthesia at donor site	**45.5** (10)	**34.8** (8)
Dissatisfied with scar	**4.55** (1)	**8.3** (2)
Satisfaction Index: Would undergo graft again/recommend to friend	**90.9** (20)	**100** (23)

Comparing our study with the study done by Pollock *et al*. (1), we had fewer patients feeling pain at the donor site post-operatively, leading to less patients having problems with ambulation. Despite this, more of our patients required walking aids post-operatively. We also had a higher incidence of paraesthesia at the donor site, but this resolved in less than a month in all the patients. Patient satisfaction with their scar compared slightly favourably for us, while the satisfaction index was favourable for Pollock *et al*.

Table 4.2: A comparison of bone graft morbidity in our study with other authors

Author	Approach	Procedure	Population	Acute Pain	Chronic Pain	Cosmesis
Our study	Anterior	ACDF	Adult	10.53% at 3 months	5.26% at 36 months	90.91% Satisfied
Pollock *et al*. (1)	Anterior	ACDF	Adult	17.4% at 15 weeks	4.2% at 14 months	92.7% Satisfied
Shamsaldin *et al*. (34)	Anterior	ACDF	Adult	10% at 2 months	6% at 12 months	Satisfactory
Sasso *et al*. (35)	Anterior	ALIF	Adult	43% at 3 months	33% at 12 months	82% Satisfied
Silber *et al*. (36)	Anterior	ACDF	Adult	N/A	26% at 24 months	92.5% Satisfied
Schnee *et al*. (26)	Anterior	ACDF	Adult	2.8% at 3 months	N/A	86.1% Satisfied
Pollock *et al*. (1)	Anterior	ACDF	Adult	73.1% at 3 weeks	1.9% at 7 months	90.2% Satisfied

4.2 Limitations

The study sample size was dependent on the accuracy of the contact details of the patients that underwent the procedure. Unfortunately, a large number of the patients' phone contact details, as registered by the hospital administrative department did not go through when called. This may be due to patients regularly changing phone service providers. This led to a relatively small sample size of the patient cohort which limited our study. Furthermore, due to the fact that this is a retrospective study, there is the problem of recall bias. A prospective study on the same topic will mitigate these limitations and may be embarked upon in the near future.

5 CHAPTER - CONCLUSION

The incidence of cervical spine pathology is quite significant in South Africa. This includes both degenerative cervical spine disease as well as traumatic cervical spine injuries. The perceived adverse effects of ICBG are not as severe as we are made to believe, and should not deter surgeons from utilizing this procedure, especially when financial cost is a factor to be considered. Our study showed the safety of the procedure and we advocate a favourable use of the ABG in cervical spine fusions performed for both degenerative and traumatic spinal conditions.

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APPENDICES

APPENDIX A – CEO Permission Letter

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Enquiries:
Ms. N. Mzila
Office of the Clinical Director
Email: Nolwazi.Mzila@gauteng.gov.za
Tell: (011): 488-4812
10 October 2019

Dear Dr. I. A. Egbunike

STUDY TITLE: Lliac Crest Donor Site Morbidity in Patients Undergoing Anterior Cervical Discectomy and Fission at Charlotte Maxeke Johannesburg Academic Hospital.

Permission to review patient file for conduction of the above mentioned study is provisional approved. Your study can only commence once Ethics approval is obtained. Please forward a copy of your Ethics Clearance Certificate as soon as the study is approved by the Ethics Committee for the CEO's office to give you the final approval to conduct the study.

Supported / ~~not supported~~

Dr. M.I. Mofokeng
Clinical Director
DATE: 10/10/2019

Approved / not approved

Ms. G. Bogoshi
Chief Executive Officer
DATE: 11.10.2019

Appendix B: Human Research Ethics Committee (Medical) Clearance Certificate

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

R14/49 Dr Ike Egbunike

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M1911139

NAME: (Principal Investigator)	Dr Ike Egbunike
DEPARTMENT:	Orthopaedics Charlotte Maxeke Johannesburg Academic Hospital
PROJECT TITLE:	Iliac Crest Donor Site Morbidity in Patients undergoing Anterior Cervical Disectomy and Fusion at Charlotte Maxeke Johannesburg Academic Hospital
DATE CONSIDERED:	29/11/2019
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr Shahzad Khan
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	11/02/2020

This clearance certificate is valid for 5 years from 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 Third Floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. 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 resubmit the application to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in **November** and will therefore be due in the month of **November** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

Date 12.02.2020

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX C – BONE GRAFT QUESTIONNAIRE

Patient's study number:

Gender:

Height:

Weight:

BMI:

1. Did you experience pain at the hip donor site, post op?
    - Yes
    - No
    - Cannot Remember

2. How much was the pain using a VAS Scale (from 1- 10)
    - …….

3. Which side was the graft taken from?
    - Right front
    - Right back
    - Left front
    - Left back

4. Any infection at the IBG site?
    - Yes
    - No

5. How long did the pain at the donor site last?
    - 1 week- 1 month
    - 1 month – 6 months
    - 6 months- 1 year
    - 1 year- 5 years
    - > 5 years

6. Did you have problems walking post bone graft?
    - Yes

- No

7. Was a walking aid (crutches, walking frame, wheel chair) needed post op?

- Yes. Duration ……..
- No

8. Was there any associated numbness around the area the IBG was taken from?

- Yes. Duration ……..
- No
- Cannot remember

9. Could the defect be felt thru the skin? For how long after the op?

- Yes. Duration …….
- No

10. Are you satisfied with the outcome of the operation?

- Yes
- No

11. Are you satisfied with the scar?

- Yes
- No

12. Would u recommend the procedure to a friend?

- Yes
- No

13. Did you experience any itching at the op site?

- Yes. Duration-
- No