



**SURGICAL SITE INFECTION PRE AND POST COVID-19-RELATED HYGIENE
PROTOCOLS IN GYNAECOLOGICAL ONCOLOGY: IS THERE A DIFFERENCE IN
PREVALENCE AND SEVERITY AT CHARLOTTE MAXEKE JOHANNESBURG
ACADEMIC HOSPITAL?**

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

Johannesburg, December 2024

DECLARATION

Declaration: Student's contribution to the article and agreement of co-authors

I, **Succes Brege Albert Bouangui-Bazolana**, Student Number **2526081**, declare that this research report is my own work and that I contributed adequately to the findings in the article submitted. It is being submitted in fulfilment of the requirement for the degree of Master of Medicine in the branch of Obstetrics and Gynaecology at the University of the Witwatersrand, Johannesburg. Assistance received has been acknowledged in the article. This work has not been submitted previously for any degree or examination at any other university.

I certify that the protocol has been approved in accordance with the Human Research Ethics Committee (Medical) at the University of the Witwatersrand, Johannesburg (Clearance Certificate M220416).

Agreement by co-authors: By signing this declaration, the co-authors below agree to the use of the article(s) by the student as part of his Research Report.

Article:

SURGICAL SITE INFECTION PRE AND POST COVID-19-RELATED HYGIENE PROTOCOLS IN GYNAECOLOGICAL ONCOLOGY: IS THERE A DIFFERENCE IN PREVALENCE AND SEVERITY AT CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL?

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2nd author/ supervisor	Langanani Mbodi		30/12/2024

DEDICATION

I dedicate this work to my God who has given me breath, health and guidance.

To my late father and to my mother for their guidance; and my siblings, thank you for your moral and financial support.

To my wife, I know this hasn't been a smooth journey but the love I have for you is real.

To my children, you are the reason I worked so hard to make this moment a reality.

ACKNOWLEDGEMENTS

To Dr Langanani Mbodi, I will never be able to thank you enough for supervising this work. Your passion for excellence has pushed me beyond my limits. Please accept my appreciation.

To Dr Evrard Nika, your contribution in proofreading is highly appreciated.

Conflict of interest

We declare no conflict of interest.

Author contributions and funding sources

SBA: Primary author, protocol redaction, ethic clearance, data collection and analysis, and manuscript preparation.

LM: Secondary author, methodology support, proofreading, clinical input, manuscript preparation, and final approval.

This publication is currently not funded by any external sources, companies, or individuals. We have applied for funding from the School of Clinical Medicine, unfortunately it has been declined.

Ethical considerations

The study was approved by the University of the Witwatersrand Human Research Ethics Committee (HREC Medical) with clearance number M220416.

Permission was obtained from the management of Charlotte Maxeke Johannesburg Academic Hospital before data collection.

The information collected was confidential. The data sheet did not include any identifiers.

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SOUTH AFRICAN MEDICAL JOURNAL (SAMJ)

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§

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 - o **Objectives:** what the study intends to find out
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 - o **Results:** first sentence must be brief population and sample description; outline the results according to the methods described. Primary outcomes must be described first, even if they are not the most significant findings of the study.
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The following are additional heading or section options that may appear within these:

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Some examples:

- *Journal references:* Price NC, Jacobs NN, Roberts DA, et al. Importance of asking about glaucoma. Stat Med 1998;289(1):350-355. <http://dx.doi.org/10.1000/hgjr.182>
- *Book references:* Jeffcoate N. Principles of Gynaecology. 4th ed. London: Butterworth, 1975:96-101.
- *Chapter/section in a book:* Weinstein L, Swartz MN. Pathogenic Properties of Invading Microorganisms. In: Sodeman WA, Sodeman WA, eds. Pathologic Physiology: Mechanisms of Disease. Philadelphia: WB Saunders, 1974:457-472.
- *Internet references:* World Health Organization. The World Health Report 2002 - Reducing Risks, Promoting Healthy Life. Geneva: WHO, 2002. <http://www.who.int/whr/2002> (accessed 16 January 2010).
- Legal references
 - Government Gazettes:

National Department of Health, South Africa. National Policy for Health Act, 1990 (Act No. 116 of 1990). Free primary health care services. Government Gazette No. 17507:1514. 1996.

In this example, 17507 is the Gazette Number. This is followed by :1514 - this is the notice number in this Gazette.

- Provincial Gazettes:

Gauteng Province, South Africa; Department of Agriculture, Conservation, Environment and Land Affairs. Publication of the Gauteng health care waste management draft regulations. Gauteng Provincial Gazette No. 373:3003, 2003.

- Acts:

South Africa. National Health Act No. 61 of 2003.

- Regulations to an Act:

South Africa. National Health Act of 2003. Regulations: Rendering of clinical forensic medicine services. Government Gazette No. 35099, 2012. (Published under Government Notice R176).

- Bills:

South Africa. Traditional Health Practitioners Bill, No. B66B-2003, 2006.

- Green/white papers:

South Africa. Department of Health Green Paper: National Health Insurance in South Africa. 2011.

- Case law:

Rex v Jopp and Another 1949 (4) SA 11 (N)

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JOURNAL ARTICLE

Abstract

Introduction: Surgical site infection is common in gynaecological oncology surgery worldwide. It constitutes a burden to patients and the healthcare system. The COVID-19 pandemic resulted in a lockdown across the globe to minimise human contact, therefore curbing the spread of the disease. Furthermore, drastic measures regarding hygiene in medical settings, particularly in operating theatres, were implemented to prevent the transmission of the virus between patients and healthcare professionals.

Objectives: This study was designed to describe the impact of COVID-19-related hygiene measures on the occurrence of surgical site infections at Charlotte Maxeke Johannesburg Academic Hospital. We hypothesised that there would be a reduction in the incidence of surgical site infections due to compliance with hygienic practices.

Methods: This was a single-centre retrospective study of participants who had elective surgery for pre-malignant lesions, malignancies or suspected malignant conditions from 1 September 2018 to 29 February 2020 (pre-COVID group), and from 1 March 2020 to 31 December 2021 (COVID group). A descriptive analysis was conducted using Stata 15.0. Surgical site infection rates, relook laparotomy, delay in adjuvant therapy, length of hospital stay and mortality were compared using Chi-squared and Fischer's tests.

Results: We included 511 participants with 296 (57.9%) being in the pre-COVID group, and 215 (42.1%) in the COVID group. There was no significant difference in the occurrence of surgical site infection. However, there was significantly prolonged hospitalisation in the COVID group ($p < 0.001$).

Conclusion: As the occurrence of surgical site infections in the pre-COVID and COVID group is almost similar and comparable, we may confidently conclude that healthcare professionals played a minimal role in the incidence of surgical site infections as hypothesised in many pre-COVID studies.

Introduction

Gynaecological cancer accounted for 14,1% of all cancers in South Africa in 2020, irrespective of gender, as reported by Globocan.^[1] Surgery remains the mainstay of treatment of pre-malignant lesions and early-stage operable malignancies, often followed by adjuvant therapy.^[2] Although most cases are being done as elective, surgical site infections (SSI) are common ^[3,4] and are a burden to the patient due to their medical (prolonged hospital admission, high morbidity, and delayed initiation of adjuvant therapy) and social implications (loss of employment)^[5] and to the healthcare system despite progress in infection control practices (improved operating room ventilation, sterilisation methods, barriers, surgical techniques and prophylactic antibiotic). Elective surgery has the advantage of allowing time to act on well-established modifiable risk factors of SSI such as smoking, obesity, uncontrolled diabetes and low CD4 count in HIV patients. ^[3,4,6,7]

Hygiene measures constitute a cornerstone of the prevention of SSI along with the administration of a prophylactic antibiotic. During the COVID-19 pandemic, lockdown was imposed, and emphasis was put on hygiene measures to curb the spread of the disease. ^[8,9] Quarantine measures were enforced and patient visits, including from healthcare professionals, were restricted in South Africa and worldwide. Strict peri-operative and intra-operative infection prevention protocols were implemented. Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) policies standardised and emphasised measures such as hand hygiene, limited personnel in operating theatre, the use of personal protective equipment, and interval disinfection of the theatre surroundings. ^[8, 9] It was speculated that these measures would reduce the risk of SSI.

This study was designed to evaluate the impact of COVID-19-related hygiene measures on the occurrence of surgical site infections at CMJAH. The objectives were to describe the demographics, determine the prevalence/incidence of wound sepsis, and assess the severity of SSI, and the association with retroviral disease.

We hypothesised that there would be a reduction in the incidence of surgical site infections due to compliance with hygienic practices; and if true, it may help to design a new preoperative, intraoperative and postoperative protocol in gynaecological oncology surgery to reduce the SSI beyond the COVID-19 pandemic.

Methods

This is a retrospective observational record review study conducted at Charlotte Maxeke Johannesburg Academic Hospital, located in Parktown, Johannesburg, in the Gynaecology Oncology Department.

Data were extracted from the Orbit DMS Application, which manages the electronic patient files at CMJAH.

Participants were allocated to a pre-COVID group (1 September 2018 to 29 February 2020) and a COVID group (1 March 2020 to 31 December 2021).

All participants whose records were available and who had undergone open or laparoscopic abdomen gynaecological oncology surgery as well as vulva and groin surgery were included in the study.

Participants who had undergone minor surgery (biopsy), surgery for benign conditions, or whose data were missing in the file were excluded. Participants with a positive COVID PCR had their surgery deferred for at least four weeks until they had returned a negative COVID PCR test.

The Orbit DMS was searched for participants' demographic details (age, sex, race), comorbidities (diabetes, hypertension, HIV), type of cancer, operative details and post-operative outcomes. The CD4 count and viral load (VL) of participants with known HIV status were measured on admission.

The primary outcomes measured were the prevalence/incidence of SSI and its severity as defined by the World Health Organization (superficial incisional, deep incisional, or organ/space SSI) and mortality.

A simple descriptive analysis was conducted to describe the characteristics of the whole study population and stratified by the study period (pre-COVID group versus COVID group).

Categorical variables were described using frequencies and percentages. Continuous variables were summarised using means (with standard deviations) for paracentric data and medians (with inter-quantile range [IQR]) for non-parametric data.

Chi-square and Fischer's exact test were used to determine any significant differences in the proportions of different characteristics and outcomes between the pre-COVID and COVID periods.

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The main outcome variable was the occurrence of surgical site infection (SSI). SSI was converted into a binary variable (SSI = 1 and no SSI = 0). Bivariate and multivariable-adjusted logistic regression models were then run to identify independent predictors of SSI. An adjustment was made for the a priori factors of age, study period, and HIV status.

All data analyses were conducted in Stata 15.0® (StataCorp, 4905 Lakeway Drive, College Station, Texas 77845 USA). A p-value of <0,05 was statistically significant.

Results

A total of 511 female participants underwent surgery for suspected, pre-malignant, or confirmed gynaecological malignancy in our study. They were distributed among 296 participants (57.9%) in the pre-COVID group and 215 participants (42.1%) in the COVID group. Prophylactic antibiotics were routinely administered to all the participants intra-operatively.

Ninety-one participants developed an SSI, for an overall incidence of 17.8%. All of them received antibiotics and 32 were taken back to the theatre for a relook laparotomy. The demographic characteristics of the 511 participants are shown in Table 1.

Table 1: Pre-operative and demographic characteristics of participants

Description	All (N=511) n (%) mean (SD) or median (iqr)	Pre-COVID (N=296) n (%) mean (SD) or median (iqr)	COVID (N=215) n (%) mean (SD) or median (iqr)	P value Fischer's exact or Chi-square or Rank sum test
Age (n=503) - mean	50.6 (13.2)	49.6 (13.1)	51.9 (13.5)	0.03
Age - < 40 - 40 to 60 - > 60	107 (21.3) 269 (53.5) 127 (25.3)	64 (21.9) 162 (55.7) 65 (22.3)	43 (20.3) 107 (50.5) 62 (29.3)	0.21
HIV status - Negative - Positive - Unknown	289 (57.2) 213 (42.2) 7 (1.3)	155 (46.1) 134 (46.1) 4 (1.3)	134 (62.6) 79 (36.9) 3 (1.4)	0.11
CD4 count (n=158) - < 200 - ≥ 200	24 (15.2) 134 (84.8)	15 (14.9) 86 (85.2)	9 (15.8) 48 (84.2)	0.88
Viral load - ≤ 20	128 (78.1)	82 (78.4)	46 (77.9)	0.99
Smoking - Non-smoker - Smoker	435 (85.1) 76 (15.0)	257 (86.8) 39 (13.4)	178 (82.8) 37 (17.2)	0.03
Body mass index (n=294) - Low - Normal - Overweight - Obese	18 (6.1) 90 (30.6) 94 (31.9) 92 (31.3)	6 (4.6) 40 (30.5) 40 (30.5) 45 (34.4)	12 (7.4) 50 (30.7) 54 (33.1) 47 (28.8)	0.25
Albumin - mean (SD)	38.8 (7.7)	38.5 (7.6)	39.1 (7.7)	0.56
Pre-operative WCC - mean (SD)	6.9 (3.5)	6.7 (3.4)	7.3 (3.6)	0.01
Comorbidities - Hypertension - Diabetes - Chronic kidney disease - Pulmonary disease	193 (37.8) 62 (12.1) 8 (1.6) 15 (2.9)	106 (35.8) 35 (11.8) 4 (1.4) 8 (2.7)	87 (40.5) 27 (12.6) 4 (1.9) 7 (3.3)	0.25
Location of cancer - Cervix cancer - Ovarian cancer - Endometrial cancer - Vulva cancer - Other cancer	213 (41.7) 152 (29.8) 86 (16.8) 47 (9.2) 13 (2.5)	152 (51.4) 70 (23.7) 37 (12.5) 29 (9.8) 8 (2.7)	61 (28.4) 82 (38.1) 49 (22.8) 18 (8.4) 5 (2.3)	< 0.001
Peri-incisional infection	7 (1.4)	4 (1.4)	3 (1.4)	0.97

The pre-COVID group and the COVID group had similar baseline pre-operative demographic characteristics in terms of age, obesity incidence, smoking, and pre-operative white cell count (WCC). The risk of developing SSI was similar in both groups, respectively 15.9% and 20.5%.

In this study, 213 participants (42.2%) were HIV-positive on anti-retroviral therapy. A total of 128 patients (78.1%) had an undetectable viral load (VL less than 20). Seventy-six patients (15.0%) were smokers. The duration of smoking and the number of cigarettes per day were not elucidated.

The body mass index (BMI) was measured only in 294 patients. Obesity was present in 92 patients (31.3%), including 35 patients (11.9%) with class III obesity (BMI above 40 kg/m²).

Hypertension and diabetes were the predominant comorbidities, affecting respectively 193 patients (37.8%) and 62 patients (12.1%).

All patients were optimised prior to surgery. The mean pre-operative haemoglobin was 12.4 g/dl (SD $\pm$ 5.4).

The mean white cell count was $6.9 \times 10^9/L$ (SD $\pm$ 3.5). The mean white cell count was $6.7 \times 10^9/L$ (SD $\pm$ 3.4) in the pre-COVID group versus $7.3 \times 10^9/L$ (SD $\pm$ 3.6) in the COVID group ($p = 0.01$). The Albumin level was not routinely assessed pre-operatively in the participants. The mean albumin level was 38.8 g/L (SD $\pm$ 7.7), similar for both study groups.

The most common indication of surgery was cervical pre-malignant lesion or malignancy, accounting for 213 cases (41.7%). However, the risk of SSI was significant in participants who had surgery for endometrial and vulva malignancy, with 25.6% and 31.9%, respectively.

Table 2 represents the intra-operative factors that may have contributed to the occurrence of SSI.

Table 2: Intra-operative characteristics of participants

Description	All (n=511)	Pre-COVID (n=296)	COVID (n=215)	P value
	n (%) mean (SD) or median (IQR)	n (%) mean (SD) or median (IQR)	n (%) mean (SD) or median (IQR)	
Mean duration cancer diagnosis to surgery (weeks)	13.6 (13.6)	20.3 (15.5)	8.9 (8.9)	< 0.001
Type of surgery				< 0.001
- Open laparotomy	352 (68.9)	201 (68.0)	151 (70.2)	
- Vaginal hysterectomy	70 (13.6)	31 (10.4)	39 (18.1)	
- Laparoscopic surgery	41 (8.0)	35 (11.8)	6 (2.8)	
- Vulvectomy	47 (9.1)	29 (9.8)	18 (8.4)	
- Vaginectomy	1 (0.2)	0 (0.0)	1 (0.4)	
Type of procedure				< 0.009
- Radical hysterectomy	44 (8.6)	27 (9.1)	17 (7.9)	
- Hysterectomy	233 (45.6)	131 (44.2)	102 (47.4)	
- Debulking (TAH = 22)	152 (29.7)	98 (33.1)	54 (25.1)	
- Vulvectomy and LND	47 (9.2)	29 (9.8)	18 (8.4)	
- Others	35 (6.8)	11 (3.7)	24 (11.1)	
Complications				0.92
- Haemorrhage	11 (2.1)	7 (2.3)	4 (1.8)	
- Bowel injury	19 (3.7)	12 (4.1)	7 (3.2)	
- Bladder/ureteric injury	6 (1.1)	3 (1.0)	3 (1.4)	
- Vascular injury	2 (0.4)	1 (0.3)	1 (0.4)	
Skin closure				< 0.001
- Clips	290 (71.1)	120 (55.6)	170 (88.5)	
- Nylon	39 (9.6)	30 (13.9)	9 (4.7)	
Mean duration of surgery	1.8 (0.9)	1.7 (0.8)	2.1 (0.9)	< 0.001

The proportion of patients in whom clips were used for skin closure was higher in the COVID group, aiming at minimizing exposure time in theatre.

The mean duration of surgery was higher during the COVID period due to implementation of peri-operative infection prevention control protocol measures enforced in line with the hospital COVID policy.

The post-operative characteristics are represented in Table 3.

Table 3: Post-operative outcomes and characteristics of participants with surgical site infection

Description	All (511)	Pre-COVID (296)	COVID (215)	P value
	n (%) mean (SD) or median (IQR)	n (%) mean (SD) or median (IQR)	n (%) mean (SD) or median (IQR)	
Surgical site infection	91 (17.8)	47 (15.9)	44 (20.5)	0.19
Severity				0.35
- Superficial	45 (52.9)	24 (55.8)	21 (50.0)	0.004
- Deep/Fascia	8 (9.4)	5 (11.6)	3 (7.1)	
- Organ/space	32 (37.7)	14 (32.6)	18 (42.9)	
Micro-organisms				
- None	81 (62.3%)	61 (70.9)	20 (45.5)	
- One	36 (27.7)	20 (23.3)	16 (27.7)	
- Two	7 (5.4)	6 (13.6)	1 (1.2)	
- Three	6 (4.6)	2 (4.6)	4 (4.7)	
Micro-organisms				
- Gram + cocci	25 (48.1)	14 (50.0)	11 (48.7)	
- P. aeruginosa	6 (12.8)	3 (12.5)	3 (13.0)	
- S. aureus	3 (6.4)	2 (8.3)	1 (4.6)	
- K. pneumoniae	2 (4.3)	2 (8.3)	0 (0)	
Management				0.10
- Antibiotics	75 (14.6)	37 (12.5)	38 (17.7)	0.04
- Vacuum dressing	11 (2.2)	3 (1.0)	8 (3.7)	
- Relook laparotomy	32 (6.3)	18 (6.1)	14 (6.5)	
Duration of hospital stay				0.84
- Mean (Days)	10.0 (8.6)	9.7 (9.3)	10.6 (7.5)	< 0.001
Outcome				
- ICU admission	16 (3.1)	10 (3.4)	6 (2.7)	0.46
- Death	18 (3.5)	9 (3.0)	9 (4.2)	0.49

The post-operative period was complicated by pulmonary embolism in 4 (0.78%) participants and 2 (0.39%) participants had relaparotomy for persistent haemorrhage.

Table 4 presents the factors associated with surgical site infection.

Table 4: Factors associated with surgical site infection

Description	N=91 n(row%)	Crude OR (95% CI)	P value	Adjusted OR* (95% CI)	P value
Period			0.19		
Pre-COVID	47 (15.9)	1		-	-
COVID	44 (20.5)	1.36 (0.86 – 2.14)			
Age					
< 40	17 (16.0)	1			
40 – 60	45 (17.2)	1.09 (0.44 – 4.97)	0.79	-	-
> 60	29 (20.7)	1.37 (0.29 – 3.55)	0.35		
HIV status					
Negative	56 (18.1)	1		-	-
Positive	35 (16.4)	1.25 (0.78 – 1.97)	0.35		
BMI					
Normal	15 (13.5)	1		1	
Overweight	10 (10.6)	0.74 (0.31 – 0.73)	0.48	0.74 (0.31 – 1.76)	0.50
Obese	28 (30.4)	2.71 (1.34 – 5.48)	0.005	2.62 (0.15 – 1.72)	0.009
Smoking					
Non-smoker	69 (15.9)	1		1	
Smoker	21 (27.6)	2.03 (1.15 – 3.57)	0.01	1.95 (1.08 – 3.52)	0.03
Diabetes					
Diabetic	15 (24.9)	1.56 (0.83 – 2.94)	0.17	1.40 (0.70 – 2.75)	0.33
Non-diabetic	76 (16.9)	1		1	
Cancer location					
Cervix	26 (12.2)	1		1	
Endometrium	22 (25.6)	1.47 (1.31 – 4.66)	0005	2.14 (1.04 – 4.41)	0.04
Ovary	24 (15.9)	1.36 (0.75 – 2.47)	0.32	1.14 (0.60 – 2.18)	0.68
Vulva	15 (31.9)	3.37 (1.61 – 7.05)	0.001	2.87 (1.31 – 6.31)	0.008
Others	4 (30.8)	3.29 (0.92 – 11.13)	0.06	2.79 (0.78 – 9.95)	0.11
Type of procedure					
No	104 (36.1)	1		1	
Yes	8 (40.0)	1.18 (0.47 – 2.98)	0.73	0.78 (0.28 – 2.16)	0.63
Peri-incision sepsis					
Present	4 (57.1)	6.34 (1.40 – 28.9)	0.02	6.75 (1.43 – 31.78)	0.02
Absent	87 (17.4)	1		1	
Skin closure					
Clips	68 (23.5)	1		1	
Nylon	12 (30.8)	1.44 (0.69 – 3.00)	0.33	1.29 (0.60 – 2.79)	0.53
Duration of surgery					
< 2 hours	55 (13.0)	1		1	
≥ 2 hours	36 (40.5)	4.52 (2.72 – 7.54)	< 0.001	4.46 (2.61 – 7.62)	< 0.001
Intra-op injury					
Present	12 (63.2)	8.85 (3.38 – 23.19)	< 0.001	9.10 (3.42 – 24.24)	< 0.001
Absent	79 (16.2)	1		1	
Hospitalisation					
< 10 days	36 (9.8)	1		1	
≥ 10 days	55 (36.2)	5.23 (3.23 – 8.48)	< 0.001	5.27 (3.18 – 8.74)	< 0.001

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Medical conditions, particularly diabetes mellitus, did not significantly contribute to the occurrence of wound sepsis.

Post-operative characteristics and surgical site infection are depicted in Table 5.

Table 5: Post-operative characteristics and surgical site infection

Characteristics	All cases (n = 511)	Surgical site infection		
		No (n = 420)	Yes (n = 91)	p Value
Mean (SD) age in years (n=502)	50.6 (13.2)	50.5 (13.4)	51.2 (12.7)	0.62
Smoking (n=505)				0.01
- No	429 (84.9)	361 (86.8)	68 (76.4)	
- Yes	76 (15.1)	55 (13.2)	21 (23.6)	
HIV (n=505)				0.07
- Negative	288 (57.1)	236 (56.9)	52 (58.4)	
- Positive	213 (42.3)	178 (42.9)	35 (39.3)	
- Unknown	3 (0.60)	1(0.2)	2 (2.2)	
CD4 count (n=158)				0.06
- ≥ 200	134 (84.8)	115 (87.1)	19 (73.1)	
- < 200	24 (15.2)	17 (12.9)	7 (26.9)	
VL (n=164)				0.89
- ≥ 20	36 (21.9)	28 (20.1)	8 (32.0)	
- < 20	128 (78.1)	111 (79.9)	17 (68.0)	
BMI (n = 294)				0.005
- Low	18 (6.1)	16 (6.6)	2 (3.78)	
- Normal	90 (30.6)	77 (31.9)	13 (24.5)	
- Overweight	94 (31.9)	84 (34.5)	10 (18.8))	
- Obese	92 (31.3)	64 (26.1)	28 (52.7))	
Comorbidities				0.33
- Hypertension	193 (37.8)	158 (37.7)	35 (18.1)	
- Diabetes	62 (12.1)	47 (11.2)	15 (24.9)	0.33
- COPD	15 (2.9)	10 (2.4)	5 (33.3)	0.71
- CKD	8 (1.6)	7 (1.7)	1 (12.5)	< 0.001
Type of cancer				0.04
- Cervix	213 (41.7)	187 (87.8)	26 (12.2)	
- Ovary	152 (29.8)	128 (84.1)	24 (15.9)	
- Endometrium	86 (16.8)	64 (74.4)	22 (25.6)	0.008
- Vulva	47 (9.2)	32 (68.1)	15 (31.9}	
- Others	13 (2.5)	9 (69.2)	4 (30.8)	

The proportion of smokers and obese participants were higher in the COVID group, probably associated to stress and lack of movement, and contributing to increasing the incidence of SSI in the COVID group.

The incidence of surgical site infection pre-COVID and during the COVID-19 pandemic is presented in Table 6.

Table 6: Incidence and severity of surgical site infection

	Overall N (%) mean (SD) or median (IQR)	pre-COVID group n (%) mean (SD) or median (IQR)	COVID group n (%) mean (SD) or median (IQR)	P value
SSI status				0.19
SSI present	91 (17.8)	47 (15.9)	44 (20.5)	
SSI absent	420 (82.2)	249 (84.1)	171 (79.5)	
HIV status (n=89)				0.85
-Positive	35 (39.3)	19 (42.2)	16 (36.6)	
- Negative	52 (58.4)	25 (55.6)	27 (61.4)	
-Unknown	2 (2.3)	1 (2.2)	1 (2.3)	
CD4 count (n=26)				0.27
- ≥ 200	19 (73.1)	9 (64.3)	10 (83.3)	
- < 200	7 (26.9)	5 (35.7)	2 (16.7)	
Bowel/bladder injury	19 (3.8)	12 (4.1)	7 (3.3)	0.62
Severity				0.55
Superficial incisional	45 (52.9)	24 (55.8)	21 (50.0)	
Deep incisional	8 (9.4)	5 (11.6)	3 (7.1)	
Organ/space	32 (37.7)	14 (30.6)	18 (42.9)	
Microorganisms				0.38
Gram positive cocci	25 (48.1)	12 (50.0)	13 (60.4)	
Pseudomonas aeruginosa	6 (12.8)	3 (12.5)	3 (13.0)	
Hospital stay duration	10.0 (8.6)	9.7 (9.3)	10.6 (7.5)	
Relook laparotomy	32 (6.3)	18 (6.1)	14 (6.5)	0.84
Mortality	18 (3.5)	9 (3.0)	9 (4.2)	0.49

The incidence of SSI was higher in the COVID group, probably affected by the high proportion of smokers and obese participants.

Discussion

The overall prevalence of surgical site infection was 17.8%, with the incidence being similar in the pre-COVID and COVID groups (15.9% vs 20.5%). This finding agreed with Atumanyire et al. ^[10] in Uganda who found a similar incidence in the COVID and pre-COVID groups (17.6% vs 16.7%) in participants who underwent emergency laparotomy surgery, considering that elective surgery is a more controlled and planned procedure. Martin et al. ^[11,12] also reported no significant difference in the risk of developing SSI among participants who had colorectal surgery in Australia. In contrast to our findings, there was a 23% decrease in the proportion of SSI following major oncological surgeries during the pandemic in India. ^[13]

Our findings demonstrate that the occurrence of SSI is not impacted by human factors (healthcare professionals) or scrubbing type (reusable linen vs non-reusable draping).

The impact of the COVID-19 pandemic on the occurrence of SSI is still a subject of controversy with different studies across the world finding contradictory and conflicting reports. ^[12,14]

Our study has demonstrated that the measures implemented during the COVID-19 pandemic did not impact or modify the occurrence of SSI following gynaecological oncology surgery. The human factor may therefore be considered negligible in the occurrence of this specific type of surgical complication.

SSI was superficial in most participants (52.9%), with organ/space being the second most common type of SSI (37.7%). This agrees with findings in Uganda ^[14] and Saudi Arabia. ^[15] Gynaecological oncology surgery is associated with an increased risk of hollow viscous injury which may explain a high proportion of organ/space SSI.

The most common indication of surgery was cervical malignancy, which accounted for 41.6%, followed by ovarian cancer where surgery was performed in 29.7% of participants. However, the location of cancer in the endometrium (25.6%, Crude OR: 2.47) and the vulva (31.9%, Crude OR: 3.37) was significantly associated with wound sepsis complication. The advanced state of the disease and the complexity of surgical procedures related to these cancers may explain this association. ^[16,17]

Age above 40 years is a non-modifiable risk factor of SSI.^[4] Most gynaecological cancers occur over the age of 45 years old, which explains the high mean age in our study. However, age was not a risk factor for the occurrence of SSI.

The HIV status of participants was not significantly associated with the occurrence of SSI in our study. Moreover, participants with a CD4 count below 200 cells/mm³ were not significantly at risk of developing SSI. This finding disagrees with the study conducted by Green et al. in South Africa^[18] Although a low CD4 count is considered a risk factor for SSI, our study showed a lack of association between low CD4 count and SSI. This may be explained by the level of control of the disease in our participants because disease control is one of the requirements for elective surgeries in our setting.

There was no association between diabetes mellitus and wound sepsis, although diabetes is considered a traditional risk factor for SSI. This may be explained by the strict glycaemic control before surgery in elective cases. Our findings are therefore contradictory to the study conducted by Martin et al.^[19] where a significant association between diabetes mellitus and SSI was evidenced prompting adequate glycaemic control before an elective procedure.

Obese patients were significantly at risk of developing surgical wound sepsis in our study. Over 30% of obese patients in our sample had surgery complicated by SSI. Our findings agree with most studies worldwide,^[20,21] and weight optimisation before surgery should be recommended.

Minimally invasive surgery such as laparoscopy has drastically contributed to reducing the incidence of SSI.^[16,17] Unfortunately, its use is limited in oncology and restricted to exploration, biopsy, and lymph node dissection in suspected recurrence cases. During the COVID-19 pandemic, laparoscopic surgeries were avoided because laparoscopy is an aerosol-generating procedure that could contribute to the spread of the virus. This may explain the low rate of SSI in this category. However, El Boghdady et al.^[22] suggested that there was no scientific evidence to date in support of the transmission of COVID-19 by laparoscopic surgery and advised that laparoscopy can be used with precautions because of its benefits compared to open surgery.

A surgical procedure lasting two hours or more has been implicated in the development of SSI^[20,23]. Our study was not an exception as this time factor was significantly associated with the occurrence of SSI.

The incidence of wound sepsis was higher in patients who had sustained intra-operative hollow viscus injury (bowel and bladder injury). These complications resulted in prolonged operative time and the extravasation of the unclean/contaminated content in the abdomen cavity. Previous studies have demonstrated the occurrence of SSI in patients whose surgery was complicated by organ injury.^[16,17]

Most of our patients had skin closure with metal clips. The sub-cutaneous skin closure was significantly associated with wound sepsis ($p = 0.002$).

Microbiology was able to identify the micro-organisms responsible for the SSI in 37.7% of the participants. *Gram-positive cocci* without identification were the predominant causative agent followed by *Pseudomonas aeruginosa*.

The lack of micro-organism identification may be explained by the lack of follow-up of the result of culture, especially in patients with superficial wound sepsis who constitute most cases of SSI and who might have been discharged while the identification process was still in progress. For the above reason, it is difficult to compare our findings with other studies across the continent or with data from Western countries. However, some studies have identified *Staphylococcus aureus* as a main causative pathogen of SSI.^[4,24,25]

The mean duration of hospitalisation of patients in whom SSI occurred was significantly higher, which agrees with most of the published studies across the globe.^[26] The socio-economic repercussions of prolonged duration of hospitalisation were beyond the objective of our study.

It has been recommended to initiate radiotherapy four to six weeks after a radical hysterectomy and it has been found that any delay may increase morbidity and mortality related to disease progression.^[27] In our study, the mean waiting period for initiation of radiotherapy after a radical hysterectomy was three months, delayed due to a backlog in the radiation oncology department. This delay was not affected by SSI occurrence as the mean healing time was three weeks.

The mortality rate was similar in both the pre-COVID and COVID periods (3.0% and 4.2%, respectively). The COVID-19 pandemic did not lead to an increase in the mortality rate in our study. The mortality rate was increased in the study conducted by Nachon-Acosta et al (27.3% in the COVID group versus 5.8% in the pre-COVID group).^[28] However, COVID-19-positive participants were included in his study while in ours, participants who tested positive for COVID-19 were considered high risk for surgery, therefore their surgery was delayed for a minimum

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period of four weeks in line with the institution's policy. This provision may explain the lack of impact of the pandemic in our study.

Limitations

This study only assessed participants who underwent elective gynaecological oncology surgery, a well-planned procedure with prior optimisation of SSI risk factors before surgery and was conducted in a single centre. It may not be a true reflection of the impact of COVID-19 on SSI in global surgical discipline.

SSI mostly develops after discharge, and we may therefore have missed some cases of SSI in participants who may have sought help from other institutions or been treated at home for cases of superficial SSI. In this regard, a prospective study could have helped cover this grey area.

Many participants were excluded because of incomplete or missing data. This might have affected the incidence of SSI in our study.

Conclusion

The risk of developing SSI during the COVID-19 pandemic remained the same as in the period prior to COVID-19 precautionary hygienic protocols. COVID-19 hygiene measures did not have an impact on the occurrence of wound sepsis. We may conclude that the human factor in the form of contamination from healthcare professionals (aerosol and contact) played a minimal role in SSI in our study. However, the incidence of SSI in our study is higher compared to western countries, suggesting that there is still room for improvement. Furthermore, given that our study only included planned elective cases of gynaecological oncology participants in a single centre, it is unclear whether a multi-centre study with a larger cohort could have yielded different results. National-level data analysis may provide more comprehensive results that can be extrapolated to the general population undergoing surgery. This may be a subject of future research projects and if confirmed, the emphasis will be on reinforcing the current recommendations in terms of SSI prevention.

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APPENDICES

Appendix A: Research Protocol



Faculty of Health Science

School of Clinical Medicine

Surgical Site Infection Pre and Post COVID-19-Related Hygiene Protocols in Gynaecological Oncology: Is There a Difference in Prevalence and Severity at Charlotte Maxeke Johannesburg Academic Hospital?

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LIST OF ABBREVIATIONS

ACS: American College of Surgeons

ASA: American Society of Anesthesiology

BMI: Body Mass Index

CDC: Center for Disease Control and Prevention

CMJAH: Charlotte Maxeke Johannesburg Academic Hospital

COPD: Chronic Obstructive Pulmonary Disease

COVID 19: Coronavirus Disease 2019

HIV: Human Immunodeficiency Virus

ICU: Intensive Care Unit

OR: Operating Room

PCR: Polymerase Chain Reaction

PPE: Personal Protective Equipment

SSI: Surgical Site Infection

WHO: World Health Organization

DEFINITION OF TERMS

Antimicrobial	Agent that kills microorganisms or inhibit their growth
Adjuvant therapy	Treatment given in addition to the primary or initial therapy to maximize its effectiveness
Germ	Microorganism that has a potential of causing infection
Elective surgery	Surgery that is scheduled in advance and is not urgent
Hospital admission	Period from admission to discharge of a patient
Operative procedure	Operative procedure is a procedure that takes place during an operation where at least one incision (including laparoscopic approach and cranial Burr holes) is made through the skin or mucous membrane, or reoperation via an incision that was left open during a prior operative procedure and takes place in an operating room (OR), defined as a patient care area that met the American Institute of Architects (AIA) criteria (26).
Surgical complication	Undesirable and unintended result of an operation affecting the patient that occurs as a direct result of the operation.

1. INTRODUCTION

1.1 Problem statement

Oncologic diseases constitute a public health burden worldwide, and even more in Africa because of limited resources. Surgery remains the mainstay of treatment for many cancers and is often followed by adjuvant treatment where indicated (1). Surgery or operative procedure treatment is associated with complications and surgical site infection is one of the major complications.

Surgical site infections are associated with prolonged hospital admission, high morbidity, social implication i.e loss of employment, and delayed initiation of adjuvant therapy (2).

There are multiple factors associated that pose a risk for SSI. It is expected that the hygiene measures that are aimed at slowing/stopping the spread of the Covid-19 pandemic may decrease the prevalence of SSI indirectly.

1.2 Justification

The findings of this study, if the hypothesis is true, may help to design a new preoperative, intraoperative, and postoperative protocol in gynaecological oncology surgery to reduce the SSI beyond the COVID-19 pandemic.

2. LITERATURE REVIEW

2.1 Epidemiology

In South Africa, in 2020, 57109 new cases of cancer were diagnosed in women according to The Global Cancer Observatory (Globocan) report. The most common locations were Breast, Cervix uteri, Colorectum, Lung and Corpus uteri. Gynecological cancers account for 14.13% of all cancer in South Africa irrespective of the gender in 2020 as reported by the Globocan (3).

2.2 Sepsis

It is a major surgical complication. It is common after a gynecological oncology surgery because cancerous diseases cause immune suppression (4).

The Third International Consensus under the World Health Organization (WHO) defines sepsis as a “life-threatening organ dysfunction caused by a dysregulated host response to infection” (5).

The mortality risk and long-term morbidity associated with sepsis is high (4).

2.3 Surgical site infection

Surgery is a procedure where at least one incision is made through the skin or mucous membrane, or a relook through an incision that was left open during a prior operation and is performed in an operating room (OR) (6).

Any contamination of the surgical incision or organ/space may result in wound infection or surgical site infection (7) which is a common postoperative complication (8).

Surgical site infection (SSI) remains an important cause of morbidity, prolonged hospital admission and mortality (2). This despite progress in infection control practices (improved OR ventilation, sterilization methods, barriers, surgical techniques, and antibiotic prophylaxis).

Surgical infection morbidity in patients with gynaecological cancer delays the commencement of adjuvant therapy and therefore contribute to disease progression. It has been suggested to commence adjuvant therapy within 4 to 6 weeks after a radical hysterectomy and any delay may increase morbidity or worsen the outcome of the oncologic condition (9).

2.3.1 Wound classification

The surgery procedure may be classified in 4 classes as described below: clean, clean-contaminated, contaminate, and dirty/infected (10).

A particular interest will be given to clean and clean-contaminated classes.

2.3.2 Classification of surgical site infection

SSI may be classified, according to the CDC (8), as superficial incisional, deep incisional and organ/space infection.

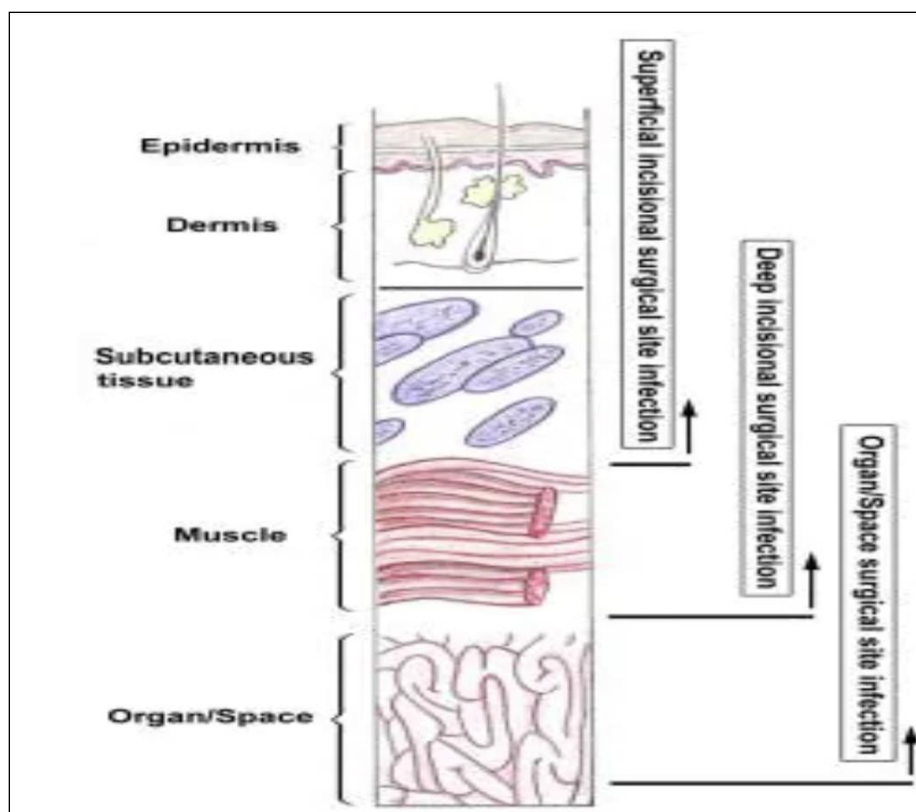


Figure 1: Classification of surgical site infection (8) (Image used with the permission from the author)

2.3.3 Risk factors

Three categories of factors that may predispose to developing SSI were described (8).

Systemic factors decrease the host resistance and affect the patient healing response. They include the patient's age (40 years or older), hypoalbuminemia, obesity, smoking habit, diabetes mellitus, pulmonary conditions, hypertension, heart failure, chronic renal diseases, cancer in advanced stage. COVID-19 is severe in patients presenting with the above-mentioned comorbidities.

Wound characteristics play a non-negligible role in the development of wound sepsis. The presence of necrotic tissue, hypothermia, the formation of hematoma, foreign body (drains) left in the wound, a dead space, the skin inadequately prepared (shaving), and the presence of an initial local or remote sepsis are contributing local factors of SSI.

Surgery characteristics were also identified as risk factors of SSI. They notably involve sub-standard hygiene, the type of surgery (laparoscopic or open surgery), the type of procedure (hysterectomy, radical hysterectomy, cytoreduction), the type of incision, surgical technique, the

Surgical Site Infection Pre and Post Covid-19-Related Hygiene Protocols: is there a difference in Prevalence and Severity at CMJAH

prolonged duration of surgery (>2 hours), intraoperative contamination (poor aseptic technique), the type of wound closure (staples or stitches), a prolonged preoperative hospital admission, the ASA score of > 2, the complexity of surgery, bowel complication.

Surgical risk increases with age beyond 40 years. O'Donnell and Kalampokas in England and Scotland found a median age of 62 and 50 years respectively (4, 11), which is in keeping with most studies except in Rwanda where the mean age was 36.5 years (12). This conflicting finding may be explained by the young age of population in Africa. Most cancer develop beyond the age 40 and Covid-19 tend to be more severe with the increasing age.

It has been demonstrated that Diabetes is an independent risk factor of SSI (13). Uncontrolled diabetes is a positive predictor for SSI, meaning that the probability of diabetic patients to develop a SSI is high. Hence the recommendation of perioperative glucose control in the prevention of SSI (7, 13).

In the US, a study conducted by Winfield et al found a direct link between obesity and morbid obesity with the development of SSI, specifically in clean and clean-contaminated surgeries (2, 14). Wound healing by primary intention is affected by cigarette smoking (8).

It has been suspected that the use of drain or skin closure with staples are predisposing factors to the development of SSI. This suspicion was confirmed by O'Donnell in his study on the "impact of surgical site infection following gynaecological cancer surgery in the UK" (4).

Poor hygiene is a predisposing and modifiable risk factor for SSI. Showering with an antiseptic has been explored and is contributing to efficiently reducing the incidence of SSI (4, 15). The shower is recommended the day prior to surgery and on the surgery day (15).

The use of minimally invasive techniques such as laparoscopy has drastically reduced the rate of SSI. Unfortunately, for gynecological oncology patients, open surgery remains the mainstay treatment. Open surgery increases the likelihood of developing SSI (4, 16), as is the type of the surgical procedure performed. The duration of surgery is one of the independent and modifiable risk factors of SSI. Prolonged surgery may result in increased risk of SSI as demonstrated by Cheng et al (17).

HIV is an important risk factor for SSI. A study conducted in Kwa-Zulu Natal by Dr Green et al shows a direct relation incidence of SSI in patient with CD4 count of less than 200. The HIV infected patients have a long hospital stay and were 36 times more likely to die from the SSI (18). This risk is probably higher in case of a concomitant Covid-19 infection.

2.3.4 Causative organisms before the Covid-19 pandemic

The patient's contamination causing SSI is commonly from his own endogenous flora. The germs may arise from the skin, the mucous membranes as well as from hollow viscera in case of accidental entry in the bowels or bladder which expose to gram-negative bacilli infection (8).

In gynecology oncology surgery, bowel commensals (especially *E. coli*) are the most frequent causative germs as reported by O'Donnell in the UK (4).

The commonest pathogens isolated causing SSI are *Staphylococcus aureus*, Coagulase-negative staphylococci, *Enterococcus* spp, *Escherichia coli*, *Enterococci*, *Enterobacter* species and *Pseudomonas aeruginosa*, *Proteus mirabilis*, *Klebsiella pneumoniae* (5, 8).

2.3.5 Hygiene measures before and after the Covid-19 pandemic

The American Council of Surgeon and the WHO have laid down a series of recommendation aiming at reducing the prevalence of the costly complication such as SSI.

Before the Covid-19 pandemic, the protocol emphasised on pre-operative showering with chlorhexidine, reducing the operating room traffic, a regular cleaning of operating environmental surface, avoiding hair removal, adequate skin preparation, maintaining asepsis, less abrasive surgical technique, improving surgical hand scrubbing and use of double gloves that should be changed for skin closure in prolonged surgery, appropriate surgical attire which may be facility-laundered scrub or disposable non-woven drapes and gowns, removal of drain as soon as possible when clinically indicated and optimal post-operative wound care (19, 20).

After the Covid-19 pandemic, the measures remain the same. But new measures were implemented to minimize the risk of nosocomial infection with Covid-19. Amongst these measures, regular hand scrubbing with an alcohol-based sanitizer for health professionals, patients, and visitors prior to and upon entry in the health facility and of the clinical wards, visitors restriction, avoiding hand shake greetings, universal use of mask for the public and use of respirators for health professionals,

use of personal protective equipment, regular theatre deep cleaning and reduced traffic in operating theatre (21).

The primary purpose of this measure is to curve the spread of the Covid-19 virus, but they may help in reducing the prevalence of SSI, thus minimizing the cost and social implication of this complication.

2.3.6 Management

Primary prevention is the management of choice of SSI. Preventing infection is efficiently done by affecting the surgical characteristics of the procedure. Acting on modifiable factors such as smoking cessation, glucose control, weight loss, preoperative showering and discouraging preoperative shaving are proven to reduce the risk of SSI (8).

The surgeon preoperative hands and forearms antiseptics and surgical attire constitute a barrier for wound contamination and infection (8).

Limiting the number of personnel, antibiotic prophylaxis (administer 30 minutes prior to the incision or at anaesthesia induction) and regular deep cleaning contribute positively to the reduction of SSI rate(22). Administration of antibiotics for prevention of SSI beyond 24 hours postoperative has not been proven to reducing the risk of infection(23). Dressing changes promote tissue granulation and wound healing by secondary intention. Few patients may need to return to theatre for relook surgery and very few will warrant an intensive care unit with almost nil mortality in gynaecology oncology patient(16). During the Covid-19 pandemic, simple measures like wearing mask or restricting visitors have emerged as promising tools for the reduction of SSI (24).

2.3.7 Other surgical outcomes

Lyer found that the commonest intraoperative complication was haemorrhage (28.7%) followed by bladder injury. In the same study, respiratory complication and thromboembolic disease were also observed (16).

2.4 COVID-19 pandemic dynamics

The hygienic measures for prevention of Covid-19 infection have been enforced as key in the fight against the pandemic. Those measures affect the patient, the surgeon as well as the surgical environment (25, 26). It remains unclear whether the micro-organisms causing SSI in

gynaecological oncology surgery patients have been affected by the strict hygiene protocol enforced in most healthcare centre during the lockdown and whether the occurrence rate of SSI has been reduced. The literature on this subject is still poor, but one may expect a reduced SSI rate and probably another predominant causative organism because of the pandemic-induced modification of lifestyle and workstyle habits.

In Mexico, Nachon-Acosta found that the commonest postoperative sepsis source in Covid-19 positive patient were intraabdominal following abdominal surgery (27). However, this study did not provide the microorganism responsible for the infection.

3. STUDY RATIONALE

SSI is a burden to the patient (prolonged admission, cost of care, delay in initiation of adjuvant therapy, loss of income ICU admission, mortality) and to the health system.

It would be of interest to see if the recommended hygienic measures imposed to the citizens and specifically to the physicians, aimed to combat or reduce the spread of current Covid-19 pandemic could have had an impact on the prevalence and severity of SSI occurrence in gynaecological oncology patients.

4. AIM AND OBJECTIVES

4.1 Aim

The aim of this study is to evaluate if the recommended hygienic practices had an impact on the surgical outcome and wound sepsis in gynaecological oncology patients who underwent surgery during the pandemic at Charlotte Maxeke Johannesburg Academic Hospital, South Africa. This will be compared with same number of years before the pandemic.

4.2 Objectives

The objectives of our study are:

1. To describe the demographics of gynaecological oncology patients who had surgery during the study period.
2. To determine the prevalence of surgical site infection during the study period.
3. To describe the associated microorganisms among gynaecological oncology patients with SSI stratified by COVID-19 pandemic.

4. To evaluate the impact of COVID-19 hygiene control measures on the occurrence of surgical site infection complications
5. To assess the length of hospital stay.
6. To assess the severity of SSI in gynaecological oncology patients who underwent surgery during the Covid-19 pandemic.

5. METHODS

5.1 Study Type

This is a retrospective observational record review study. The study will comprise a study group (post COVID-19 regulations) and control group (pre-COVID-19 regulation) on equal number of months.

5.2 Study Site

The study will be conducted at Charlotte Maxeke Johannesburg Academic Hospital, located in Parktown, Johannesburg, in the Gynaecology Oncology Department.

The site was affected by a fire incident on the 15 April 2021 which led to its closure. Clinical activities resumed in August 2021 and the first gynaecological oncology surgery were performed on the 16 August 2021. Hence the study site was closed for 4 months, affecting the timeframe duration of the study group which must be extended by 4 months.

5.3 Inclusion criteria

Data will be collected retrospectively on both control and study groups. Based on the above, the group of gynecological oncology surgery patients from 1st September 2018 to 29th February 2020 (18 months) was considered the control group and the exposed group was the group at and after 1st March 2020 to 31st December 2021 (22 months).

The exposed group data collection period has been extended by 4 months due to the fire incident that forced the closure of CMJAH for 4 months.

This study will include all patients who underwent major gynaecological oncology surgery including open abdominal surgery and vulva and groin surgery.

5.4 Exclusion criteria

Patients who underwent surgery, including minor surgery, for non-cancer conditions will be excluded from this study.

Patients who underwent gynecological oncology surgery after the CMJAH fire in different satellite hospitals will be excluded from this study.

5.5 Sample size

The expected sample size is 234 patients per each study group.

The Gynaecological Oncology unit operate a minimum of three (3) patients a week with confirmed malignancy. Over the 36-month period, this is estimated to 468 patients. We expect a 10% loss due to unavailability of files or missing data.

5.6 Data collection

The collection will extend from 31 December 2021 to, retrospectively, 1 March 2020 for the study group (22 months) and from 29 February 2020 to 1 September 2018 (18 months) for the control group.

The list of all patients who underwent surgery will be obtained from the department of gynaecology oncology register book and from the theatre register book.

A data sheet will include the following: demographics, comorbidities, period from diagnosis of cancer to surgery, HIV status, period of diagnosis of SSI from surgery, type of SSI, Pus swab result, treatment of SSI received, need for relook /repeat surgery, length of stay, outcome of treatment and other complications. The outcome to be measured is the SSI and its severity.

6. DATA ANALYSIS

Quantitative data analysis will be conducted. Descriptive analysis i.e. frequencies for categorical data and measures of central tendency for continuous data will be computed. Association between key outcomes and potential risk factors will be assessed with logistic regression after adjusting for potential confounders. All analyses will be conducted in STATA 13 with a p-values of significance set at 5%.

The two groups will be compared in terms of selected variables using a chi 2.

7. ETHICS

Permission will be sought from the Chief Executive Officer (CEO) of Charlotte Maxeke Johannesburg Academic Hospital with the aim to have access to patient's records and to conduct study in the facility. Permission will also be sought from the Head of Gynaecological Oncology Unit and Head of Department of Obstetrics and Gynaecology at the Charlotte Maxeke Johannesburg Academic hospital.

We will seek a permission from the National Health Laboratory Service (NHLS) to access full microbiology results.

The study will be registered with the National Health Research Database (NHRD).

The study will utilise the HREC clearance of the main COVID study (Clearance certificate NO. M200742) underway at CMJAH which the Gynaecological Oncology unit is participating. Permission will be requested from the lead investigator (Professor TE Luvhengo) in this COVID study.

All personal patients' related identification information will be removed for the sake of anonymity and patients will be allocated a study number.

8. TIMING

Table 1: Study timelines

	Jan 2021	Feb 2021	Mar 2021	Apr 2021	May 2021	Jun 2021	Jul 2021	Aug 2021	Sep 2021	Oct 2021	Nov 2021	Dec 2021	Jan 2022	Feb 2022	Mar 2022	Apr 2022	May 2022
Literature review																	
Preparing protocol																	
Protocol assessment																	
Ethics application																	
Collecting data																	
Data analysis																	
Writing up																	
Submission																	

9. FUNDING

The lead investigator will be responsible for all costs of the study including photocopy, travel, data analysis by a statistician and professional proofreading and editing of the final document.

Activity	Quantity	Cost per Unit	Subtotal Cost
Printing Protocol	5 x 27 pages	80c/page	R108.00
Data Analysis	1	R7000	R7000.00
Professional Proofreading	1	R4000	R4000.00
Total			R11,108.00

10. APPENDIX

APPENDIX A: Data Collection Sheet

Study/Control # SSI

Yes		No	
-----	--	----	--

Group:

Control (1 st September 2018 to 29 th February 2020)		Study (1 st March 2020 to 31 st August 2021)	
--	--	--	--

Patient Demographics

Age: (in years)		Race	African	White	Coloured	Indian	Other (specify)

Habits and Co-morbid diseases

Smoker	Yes		No	Unknown		
HIV	Positive		Negative		Unknown	
	CD4 count (Last value before surgery and date)			Viral load (Last value before surgery and date)		
ARVs (if positive)	Yes		No		Duration of use	
BMI						
Med Conditions	DM		HPT		Chronic Renal dx	Pulmonary
	Others (specify)					

Other factors

Preop Hb		Preop WCC		Preop Albumin	
Any peri-incisional pre-existing infection	Yes		No	Unknown	
Intra-operative Bowel complications		Date of surgery		Duration of surgery (hrs)	
Skin closure	Clips		Nylon	Subcutaneous suture	

Pathology/Cancer

Cervix		Endometrium		Ovary		Vulva		Others	
Type of surgery									
Date of diagnosis of cancer									
Date of diagnosis of SSI									
Date of adjuvant therapy									
Diagnosis of Cancer to surgery duration (weeks)				Surgery to SSI period (weeks)					

SSI

Microorganisms grown	1.				Day post op cultured			
	2.				Day post op cultured			
	3.				Day post op cultured			
Severity	Superficial skin			Deep fascia		Organ space/NEC Fasciitis		
Management	Wound Dressing			Vac Dressing		Debridement		Antibiotics
	Relook							
Antibiotics list								

Outcome

Date of admission							
Date of discharge/demise							
Number of days hospitalised							
Number of weeks until healing							
Need for reconstruction (If yes, where)	Yes		No		Unknown		
Need for skin graft	Yes		No		Unknown		
ICU admission	Yes		No		Unknown		
Demised	Yes		No		Unknown		

11. REFERENCES

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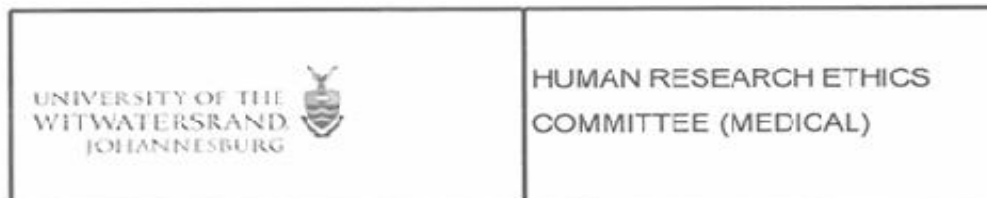
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Appendix B: HREC Clearance Letter



Office of the Deputy Vice-Chancellor (Research and Innovation)

TO: Dr SBA Bouangui-Bazolana
School of Clinical Medicine
Department of Obstetrics and Gynaecology
Medical School
University

E-mail: bouanguis@gmail.com

CC: Supervisor: Dr I. Mbofi
<mlangi2005@yahoo.co.uk>
and <HREC-Medical Research Office@wits.ac.za>

FROM: Mr Iain Burns
Human Research Ethics Committee (Medical)
Tel: 011 717 1252

E-mail: Iain.Burns@wits.ac.za

DATE: 2022/08/31

REF: R14/49

PROTOCOL NO: M220416 (This is your ethics application reference number. Please quote it in all enquiries, oral or written, relating to this study.)

PROJECT TITLE: *Surgical site infection pre- and post-Covid-19-related hygiene protocols: is there a difference in prevalence and severity at Charlotte Maxeke Johannesburg Academic Hospital?*

Please find attached the Clearance Certificate for the above project. I hope it goes well and that an article in a recognized publication comes out of it. This will reflect well on your professional standing and contribute to Government funding of the University.



MS\Works2000\Iain0007\Clearescan.wps

Appendix C: HREC Clearance Certificate


UNIVERSITY OF THE
WITWATERSRAND
JOHANNESBURG

R49 Dr SBA Bouangui-Bazolana

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M220416

NAME: Dr SBA Bouangui-Bazolana
(Principal Investigator)

DEPARTMENT: School of Clinical Medicine
Department of Obstetrics and Gynaecology
Medical School
University

PROJECT TITLE: *Surgical site infection pre- and post-Covid-19-related hygiene protocols: is there a difference in prevalence and severity at Charlotte Maxeke Johannesburg Academic Hospital?*

DATE CONSIDERED: 2022/04/29

DECISION: Approved unconditionally

CONDITIONS:

NOTE: If contact information regarding student study participants is required, please contact the Registrar's office - <Nicoleen.Potgieter@wits.ac.za>

SUPERVISOR: Dr L Mbodi

APPROVED BY: 
Dr CB Penny, Chairperson, HREC (Medical)

DATE OF APPROVAL: 2022/08/31

This Clearance Certificate is valid for 5 years from the date of approval. An extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and ONE COPY returned to the Research Office secretariat 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 April and therefore reports and re-certification will be due in the month of April each year. Unreported changes to the study may invalidate the clearance given by the HREC (Medical).

Signature of Principal Investigator

Date

Appendix D: Protocol acceptance letter



Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172076

Reference: Mrs Sandra Benn
E-mail: sandra.benn@wits.ac.za

14 February 2022
Person No: 2526081
PAG

Dr SBA Bouangui-Bazolana
Postnet
Parkrand Piazza Shop 9
Parkrand
1459
South Africa

Dear Dr Succes Bouangui-Bazolana

Master of Medicine in Obstetrics and Gynaecology: Approval of Title

We have pleasure in advising that your proposal entitled *Surgical site infection pre and post Covid-19-related hygiene protocols in gynaecologic oncology: Is there a difference in prevalence and severity at Charlotte Maxeke Johannesburg Academic Hospital?* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Sandra Benn'.

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences



Appendix E: Further training certificates



University of the Witwatersrand
Faculty of Health Sciences

Re: Online FAHS1595 Research Methodology Course

This is to confirm that **Dr Succes Brege Albert Bouangui-Bazolana**, completed the course entitled “Online FAHS1595 Research Methodology Course” which was offered by the Faculty Research Office in the Faculty of Health Sciences, University of the Witwatersrand in 2023.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Maria', is positioned above a horizontal line.

Professor Maria Papathanasopoulos

Assistant Dean: Research and Postgraduate Support



**Zertifikat
Certificat**

**Certificado
Certificate**

Promouvoir les plus hauts standards éthiques dans la protection des participants à la recherche biomédicale
Promoting the highest ethical standards in the protection of biomedical research participants



Certificat de formation - Training Certificate

Ce document atteste que - this document certifies that

SUCCES BOUANGUI-BAZOLANA

a complété avec succès - has successfully completed

Introduction to Research Ethics

du programme de formation TRREE en évaluation éthique de la recherche
of the TRREE training programme in research ethics evaluation

Release Date: 2021/05/24
CID : aQ8a9ps8La

Professeur Dominique Sprumont
Coordonateur TRREE Coordinator



Continuing Education Program
Programme de formation continue

Ce programme est soutenu par - This program is supported by :

European and Developing Countries Clinical Trials Partnership (EDCTP) (www.edctp.org) - Swiss National Science Foundation (www.snf.ch) - Canadian Institutes of Health Research (<http://www.cihr-irsc.gc.ca/2091.html>) -
Swiss Academy of Medical Sciences (SAMS/ASSM/SAMW) (www.sams.ch) - Commission for Research Partnerships with Developing Countries (www.kfp.ch)

[REV - 20170310]



Zertifikat
Certificat

Certificado
Certificate

Promouvoir les plus hauts standards éthiques dans la protection des participants à la recherche biomédicale
Promoting the highest ethical standards in the protection of biomedical research participants



Certificat de formation - Training Certificate

Ce document atteste que - this document certifies that

SUCCES BOUANGUI-BAZOLANA

a complété avec succès - has successfully completed

Research Ethics Evaluation

du programme de formation TRREE en évaluation éthique de la recherche
of the TRREE training programme in research ethics evaluation

Release Date: 2021/06/02

CID : 105AD16167

Professeur Dominique Sprumont
Coordonateur TRREE Coordinator



Continuing Education Program (3 Credits)
Programme de Formation continue (3 Crédits)

Federatio
Pharmaceutica
Helvetica

FPH

Programmes de formation
continue

Continuing Education Programs
Programas de formación continua

Ce programme est soutenu par - This program is supported by :

European and Developing Countries Clinical Trials Partnership (EDCTP) (www.edctp.org) - Swiss National Science Foundation (www.snf.ch) - Canadian Institutes of Health Research (<http://www.cihr-isc.gc.ca/cihr/2001.html>) -
Swiss Academy of Medical Science (SAMS/ASSM/SAMW) (www.sams.ch) - Commission for Research Partnerships with Developing Countries (www.adpc.ch)

[REV : 20170110]



Zertifikat Certificat

Certificado Certificate

Promouvoir les plus hauts standards éthiques dans la protection des participants à la recherche biomédicale
Promoting the highest ethical standards in the protection of biomedical research participants



Certificat de formation - Training Certificate

Ce document atteste que - this document certifies that

SUCCES BOUANGUI-BAZOLANA

a complété avec succès - has successfully completed

Informed Consent

du programme de formation TRREE en évaluation éthique de la recherche
of the TRREE training programme in research ethics evaluation

Release Date: 2021/06/11
CID : amsaox029

Professeur Dominique Sprumont
Coordinateur TRREE Coordinator



Ce programme est soutenu par - This program is supported by :

European and Developing Countries Clinical Trials Partnership (EDCTP) (www.edctp.org) - Swiss National Science Foundation (www.snf.ch) - Canadian Institutes of Health Research (<http://www.cihr-irsc.gc.ca/2091.html>) - Swiss Academy of Medical Science (SAMS/ASMS/AMSW) (www.sams.ch) - Commission for Research Partnerships with Developing Countries (www.kpdc.ch)

[REV : 20170310]



Zertifikat Certificat

Certificado Certificate

Promouvoir les plus hauts standards éthiques dans la protection des participants à la recherche biomédicale
Promoting the highest ethical standards in the protection of biomedical research participants



Certificat de formation - Training Certificate

Ce document atteste que - this document certifies that

SUCCES BOUANGUI-BAZOLANA

a complété avec succès - has successfully completed

Good Clinical Practice (GCP-E6(R2) 2016)

du programme de formation TRREE en évaluation éthique de la recherche
of the TRREE training programme in research ethics evaluation

Release Date: 2021/06/13
UCID: AASFR54276

Professeur Dominique Sprumont
Coordinateur TRREE Coordinator



Ce programme est soutenu par - This program is supported by :

European and Developing Countries Clinical Trials Partnership (EDCTP) (www.edctp.org) - Swiss National Science Foundation (www.snf.ch) - Canadian Institutes of Health Research (<http://www.cihr-irsc.gc.ca/2001.html>) - Swiss Academy of Medical Science (SAMS/ASSM/SAMW) (www.sams.ch) - Commission for Research Partnerships with Developing Countries (www.kdpc.ch)

[REV : 20181124SL]

Appendix F: CMJAH permission



GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Office of the Head of Department: Obstetrics and Gynaecology
Enquiries: Dr L. Chauke

Tel: 011 438-3179
Fax: 011 643-2522

09 September 2021

Ms Bogoshi
CEO
Charlotte Maxeke Johannesburg Academic Hospital
Parktown
Johannesburg

Dear CEO

Re: Request to conduct research titled:

Permission to obtain: Surgical Site Infection Pre and Post Covid-19-Related Hygiene Protocols:
Is there a Difference in [Prevalence and Severity at Charlotte Maxeke Johannesburg Hospital :
Dr Success Brege Albert Bouangui-Bazolana

The above matter refers. I have looked at the protocol and **satisfied to recommend** that he be granted permission to conduct the study as proposed. The candidate has also satisfied the requirements of the Wits Human Research Committee.

Thank you

Prof H. L. Chauke
Chief Specialist and Clinical Head
Department of Obstetrics and Gynaecology
Charlotte Maxeke Johannesburg Hospital and the University of the Witwatersrand

Appendix G: CMJAH study approval



Enquiries: Ms N. Mzila

Email: Nolwazi.Mzila@gauteng.gov.za

Tel: 011 488 3365

Ref: 1/7/2

Date: 19 July 2022

GP_202109_035

Dear Dr SUCCES BREGE ALBERT BOUANGUI-BAZOLANA

RE: PROVISIONAL APPROVAL OF STUDY

TITLE: SURGICAL SITE INFECTION PRE AND POST COVID-19-RELATED HYGIENE MEASURES: IS THERE A DIFFERENCE IN PREVALENCE AND SEVERITY AT CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL?

Permission to conduct the above-mentioned study is provisionally granted subject to:

1. Submitting an Ethics Clearance Certificate from the University of Witwatersrand Human Research and Ethics Committee (HREC).

Please submit the above documents at your earliest convenient within 3 months from the date of this letter. This will prompt the Chief Executive Officer (CEO) of Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) to grant you a final approval. It is important to note that your research can only commence once a final approval is granted. Failure to comply with the above-stated requirements may result in the withdrawal of your application.

Supported / Not Supported

Signed by: J. Punwasi
Signed on: 2022-07-20 10:28:28 +0200
Reason: Withdrawing Application

Dr J. Punwasi
Senior Clinical Manager

Approved / Not Approved

Signed by: Ms. G. Bogoshi
Signed on: 2022-07-20 10:28:28 +0200
Reason: Withdrawing Application

Ms. G. Bogoshi
Chief Executive Officer: CMJAH

Enquiries: Ms N. Moko
Email: Nidzwani.Moko@gautech.gov.za
Tel: 011 488 3365
Ref: 1/7/2
Date: 21 September 2022

GP_202109_035

Dear Dr SUCCES BREGE ALBERT BOUANGUI-BAZOLANA

RE: FINAL APPROVAL OF STUDY

TITLE: SURGICAL SITE INFECTION PRE AND POST COVID-19-RELATED HYGIENE MEASURES: IS THERE A DIFFERENCE IN PREVALENCE AND SEVERITY AT CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL?

Permission is granted for you to conduct the above-mentioned study as described in your request provided:

1. Charlotte Maxeke Johannesburg Academic Hospital will not in any way incur or inherit costs as a result of the said study.
2. Your study shall not disrupt services at the study sites.
3. Strict confidentiality shall always be observed.
4. Informed consent shall be solicited from patients participating in your study.

Please liaise with the HOD and Unit Manager or Sister in charge to agree on the dates and time that would suit all parties.

Kindly forward this office with the results of your study on completion of the research.

Supported/Not-Supported
Agreement to Support Program
Agreed on 2022/09/21 10:16:54 AM
Please Forwarding Study to Hospital

Dr J. Punwasi
Senior Clinical Manager

Approved/Not-Approved
Agreement to Support Program
Agreed on 2022/09/21 10:16:54 AM
Please Forwarding Study to Hospital

Ms. G Bogoshi
Chief Executive Officer

Appendix H: Plagiarism report

Turnitin document 2.docx

by Succes Bouangui-Bazolana

Submission date: 03-Oct-2024 10:08PM (UTC+0200)
Submission ID: 2474093649
File name: Turnitin_document_2.docx (54.94K)
Word count: 4337
Character count: 22429

Abstract

Introduction: Surgical site infection is common in gynaecological oncology surgery worldwide. It constitutes a burden to patients and to the healthcare system. The COVID-19 pandemic resulted in a lockdown across the globe to minimise human contact, therefore curbing the spread of the disease. Furthermore, drastic measures regarding hygiene in medical settings, particularly in operating theatres, were implemented to prevent the transmission of the virus between patients and healthcare professionals.

Objectives: This study was designed to describe the impact of COVID-19-related hygiene measures on the occurrence of surgical site infection at Charlotte Maxeke Johannesburg Academic Hospital. We hypothesised that there would be a reduction in the incidence of surgical site infection due to compliance with hygienic practices.

Methods: This was a single-centre retrospective study of participants who had elective surgery for pre-malignant lesions, malignancies, or suspected malignant conditions from 1 September 2018 to 29 February 2020 (pre-COVID group), and from 1 March 2020 to 31 December 2021 (COVID group). A descriptive analysis was conducted using Stata 15.0. Surgical site infection rates, relook laparotomy, delay in adjuvant therapy, length of hospital stay and mortality were compared using Chi squared and Fischer's tests.

Results: We included 511 participants with 296 (57.9%) being in the pre-COVID group, and 215 (42.1%) in the COVID group. There was no significant difference in the occurrence of surgical site infection. However, there was significantly prolonged hospitalisation in the COVID group ($p < 0.001$).

Conclusion: As the occurrence of surgical site infection in the pre-COVID and COVID group is almost similar and comparable, we may confidently conclude that healthcare professionals played a minimal role in the incidence of surgical site infection as hypothesised in many pre-COVID studies.

Introduction

Gynaecological cancer accounted for 14,1% of all cancers in South Africa in 2020, irrespective of gender, as reported by Globocan.^[1] Surgery remains the mainstay of treatment of pre-malignant lesions and early-stage operable malignancies, often followed by adjuvant therapy.^[2] Although most cases are being done as elective, surgical site infections (SSI) is common^[3-6] and is a burden to the patient due to its medical (prolonged hospital admission, high morbidity, and delayed initiation of adjuvant therapy) and social implications (loss of employment)^[3] and to the healthcare system despite progress in infection control practices (improved operating room ventilation, sterilisation methods, barriers, surgical techniques, and prophylactic antibiotic). Elective surgery has the advantage of allowing time to act on well establish modifiable risk factors of SSI such as smoking, obesity, uncontrolled diabetes and low CD4 count in HIV patients.^[5,6,7]

Hygiene measures constitute a cornerstone of prevention of SSI along with the administration of a prophylactic antibiotic. During the COVID-19 pandemic, the lockdown was imposed and emphasis was put on hygiene measures to curve the spread of the disease.^[8,9] Quarantine measures were enforced and patient visits, including from healthcare professionals, were restricted in South Africa and worldwide. Strict peri-operative and intra-operative infection prevention protocols were implemented. Charlotte Maxeke Johannesburg Academic Hospital policies have standardised and emphasise measures such as hand hygiene, limited personnel in operating theatre, the use of personal protective equipment and interval disinfection of the theatre surroundings.^[8,9] It was speculated that these measures would reduce the risk of SSI.

¹ The aim of our study was to evaluate the impact of the recommended hygienic practices on the surgical outcome and wound sepsis in gynaecological oncology patients who underwent surgery during the pandemic at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), South Africa, in comparison to the pre-pandemic era. We hypothesised that the hygiene measures implemented during the COVID-19 would decrease the incidence of SSI; and if true, it may help to design a new preoperative, intraoperative, and postoperative protocol in gynaecological oncology surgery to reduce the SSI beyond the COVID-19 pandemic.

for COVID-19 were considered high risk for surgery, therefore their surgery was delayed for a minimum period of four weeks in line with the institution's policy. This provision may explain the lack of impact of the pandemic in our study.

Limitations

This study only assessed participants who underwent elective gynaecological oncology surgery, a well-planned procedure with prior optimisation of SSI risk factors before surgery and was conducted in a single centre. It may not be a true reflection of the impact of COVID-19 on SSI in global surgical discipline.

SSI mostly develops after discharge and we may therefore have missed some cases of SSI in participants who may have sought help from other institutions or been treated at home for cases of superficial SSI. In this regard, a prospective study could have helped cover this grey area.

Many participants were excluded because of incomplete or missing data. This might have affected the incidence of SSI in our study.

Conclusion

The risk of developing SSI during the COVID-19 pandemic remains the same as the estimated risk prior to COVID-19 era. It is clear that COVID-19 hygiene measures did not have an impact on the occurrence of wound sepsis. We may conclude that the human factor in the form of contamination from healthcare professionals played a minimal role in SSI in our study. However, given that our study only included planned elective cases of gynaecological oncology participants in a single centre, it is unclear whether a multi-centre study with a larger cohort could have yielded different results. National-level data analysis may provide more comprehensive results that can be extrapolated to the general population undergoing surgery. This may be a subject of future research projects and if confirmed, the emphasis will be on reinforcing the current recommendations in terms of SSI prevention.

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Appendix I: Plagiarism declaration



DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE STUDENTS

SENATE PLAGIARISM POLICY:

I **Succes Brege Albert Bouangui-Bazolana** (Student number: 2526081) am a student registered for the degree of Master of Medicine (MMed) in the specialty of Obstetrics and Gynaecology in the academic year 2024.

I hereby declare the following:

- I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
- I confirm that the work submitted for assessment for the above degree is my own unaided work except where I have explicitly indicated otherwise.
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