










Wound complications after vulvar surgery in HIV-positive women treated at a teaching hospital in Johannesburg, South Africa

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Background. Vulvectomy is commonly performed for vulvar squamous cell carcinoma. The type of surgery is associated with varying rates of wound complications. In the South African medical literature, there is a lack of studies reporting on wound complications after vulvar surgery and organisms cultured in HIV-positive individuals with vulvar wound sepsis.

Objectives. To determine the incidence of wound complications after vulvectomy in HIV-positive and HIV-negative patients (primary outcome). The secondary objective was to determine the microbial organisms cultured in patients with wound sepsis.

Methods. This was a quantitative study with a study group (HIV-positive patients) and a control group (HIV-negative patients). It was a nested case-control study using the vulvar surgery database from a previous study conducted at Charlotte Maxeke Johannesburg Academic Hospital, Johannesburg, that included all patients who underwent operations on the vulva, irrespective of the indication and type of surgery, from 1 January 2013 to 31 December 2018.

Results. Postoperative complications of vulvar surgery were more common in HIV-positive patients (sepsis 18.0%, wound breakdown 15.9%, flap necrosis 1.1%, lymphocysts 1.1%) than in those who were HIV negative. The organisms cultured in the HIV-positive group, in descending order of prevalence, were *Pseudomonas aeruginosa*, *Proteus mirabilis*, and *Morganella morganii*, *Klebsiella pneumoniae*, *Enterococcus faecium* and *Candida albicans*, with equal prevalences.

Conclusions. The study findings may warrant review of the choice of prophylactic and empirical antibiotics administered pre- and postoperatively to HIV-positive patients undergoing vulvar surgery, to improve patient outcomes.

Keywords. Vulvar surgery, wound complications, wounds in HIV patients, sepsis, breakdown.

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This research project was undertaken as a requirement for completion of the MB BCh degree at the University of the Witwatersrand. The student team – Trésor Kabamba, Deborah Odendaal, Kayleigh-Jade Rose, Mulondoti Tshishonga, Lebogang Kgomo and Sholeen Moodley – collaboratively selected the topic because of its relevance and potential to enhance HIV management. Their shared interest in evidence-based medicine and improving patient outcomes guided their approach, reflecting a commitment to research that can contribute to meaningful advancements in clinical practice. The project was undertaken with the support and guidance of Dr Langanani Mbodi (study conceptualiser), Dr Venus Salem (original data collector), and Dr Admire Chikandiwa (statistician).

Vulvectomy, defined as total or partial removal of the vulva, is commonly performed for vulvar squamous cell carcinoma. Rarer indications include melanoma, Bartholin's gland carcinoma, and extramammary Paget's disease of the vulva. Vulvectomy is associated with numerous postoperative complications, including wound dehiscence, infection and haemorrhage.

HIV is an acquired immunocompromising condition that can predispose to poor wound healing outcomes. The objective of this study was to determine the effect of HIV status on the outcomes of post-vulvectomy wounds. We aimed to describe the demographic and clinical characteristics of the study and control groups, the complication rates, micro-organisms cultured in cases of wound sepsis, and the association

between HIV status and micro-organisms, wound healing and outcomes.

Methods

Study design

This was a quantitative study with a study group (HIV-positive patients) and a control group (HIV-negative patients). Both groups were retrospective populations over the study period of 6 years from 1 January 2013 to 31 December 2018.

Study setting

In a previous study, patient information was obtained from the database in the gynaecological oncology unit in the Department of Obstetrics and Gynaecology, Charlotte Maxeke Johannesburg Academic Hospital (CMJAH). CMJAH is a tertiary/referral hospital for the hospitals and clinics in greater Johannesburg.

Study population and sample size considerations

This study was a nested case-control study of the vulvar surgery database from a previous study conducted at CMJAH and including all patients who underwent operations on the vulva, irrespective of the indication and type of surgery, as per the study definitions. The patient population included those who were HIV positive and those who were HIV negative (as controls). From published literature at the time of conception of the present study, we anticipated that HIV-positive patients would have higher rates of wound complications than HIV-negative patients (25% v. 5%).^[1] Based on this assumption, a total sample size of 144 patients in the ratio of 3 HIV positive to 1 HIV negative (i.e. 108:36) was required to detect this difference at a 5% significance level (alpha level) with 80% power. The database had 113 study subjects, 89 HIV positive and 24 HIV negative, which has ~70% power to detect differences between the two groups.

Inclusion and exclusion criteria

The study included all patients aged ≥ 18 years with a histologically confirmed diagnosis of a vulvar lesion (malignant or benign) who were managed by surgical intervention (wide local excision, vulvectomy, excisional biopsy, inguinal lymphadenectomy, and advancement flaps). Patients in whom surgical management of the vulvar pathology was not confirmed or clearly defined were excluded.

Data collection

The study used secondary data from an MMed (O&G) project. Relevant data were extracted from this database into an Excel spreadsheet (2016; Microsoft, USA) as is (coded and cleaned). Data on infective micro-organisms cultured from patients with wound sepsis were extracted from or confirmed by the National Health Laboratory Service Labtrack online system. Permission to use the dataset was granted by the original researcher/gatekeeper, and access to raw data was also granted. The data were collected retrospectively for the 6-year period January 2013 - December 2018.

Ethical considerations

Permission to conduct the study was granted by the clinical head of Obstetrics and Gynaecology, head of the gynaecological oncology unit at CMJAH. The study was approved by the office of the CEO, CMJAH,

registered with the National Research Database, and approved by the University of the Witwatersrand Human Research Ethics Committee (ref. no. M220938). No patients or healthcare workers were interviewed in this study. The secondary data were accessed and used with permission from the original researcher/gatekeeper.

Data analysis

Categorical variables were summarised by frequency and percentage tabulations and illustrated through bar charts where appropriate. The Shapiro-Wilk test was conducted to ascertain normality of all continuous variables. Continuous variables were summarised by medians and interquartile ranges, as their distributions were non-parametric. Fisher's exact test was used to determine the association between HIV status and various categorical outcomes. The primary outcome was wound complications such as sepsis and breakdown, and the secondary outcome was cultured organisms in patients with wound sepsis. The overall complication rate was calculated per group by dividing the total number of complications by the total number of patients in each group. The χ^2 test could not be used as some of the cell frequencies were small (i.e. <5). The rank-sum test was used to evaluate associations between HIV status and continuous variables. A p -value <0.05 was considered statistically significant. All analyses were conducted in Stata 15.0 (StataCorp, USA).

Results

The demographics and clinical characteristics of the patients in the two groups are set out in Table 1. Vulvar pathologies in younger women (<40 years) were more common in those who were HIV positive. The median age for HIV-negative women with these pathologies was 59 years ($p<0.001$). HIV-positive women were more likely to be premenopausal (88.8%) compared with HIV-negative women (29.2%) ($p<0.001$). Premalignant and benign lesions were more common in HIV-positive patients than in those who were HIV negative ($p=0.04$).

In both groups, the commonest presentation was a growth on the vulva and the least common was bleeding. Of the 89 HIV-positive women, 83 (93.3%) presented with a growth, 9 (10.1%) had a growth and pain, and only 1 (1.1%) had a growth and bleeding. All of the 24 HIV-negative patients (100%) presented with a growth, 2 (8.3%) had a growth and pain, and 1 (4.2%) had a growth with inflammation.

In both groups, the commonest histological diagnosis was squamous cell carcinoma ($n=45$ (50.6%) of the HIV-positive patients and $n=14$ (58.3%) of those who were HIV negative). In the HIV-positive group, 21 (23.6%) of the patients had severe vulvar dysplasia (vulvar intraepithelial neoplasia (VIN) 3), 12 (13.5%) condylomas, 3 (3.4%) VIN 1, 3 (3.4%) VIN 2, 2 (2.3%) infective lesions, and 3 (3.4%) other lesions. In the HIV-negative group, VIN III was the commonest premalignant lesion ($n=5$; 20.8%). Uncommon vulvar lesions were only reported in the HIV-negative group, with 1 (4.2%) each for melanoma, lichen sclerosus and lymphoid hyperplasia. Table 2 lists the surgical procedures performed in the two groups as per indications.

Of the 89 HIV-positive patients, 78 had virological suppression (viral load <200 copies/mL) and 7 had a viral load >200 copies/mL; data were missing for the remaining 4 patients.

With regard to CD4 count status, of the 89 HIV-positive patients, 33 had a count of 500 - 1 500 cells/ μ L (no significant immunosuppression according to the World Health Organization classification), 10 had a

Table 1. Demographics and clinical characteristics of the patients in both groups (N=113)

Description	HIV positive (n=89), n (%) [*]	HIV negative (n=24), n (%) [*]	p-value [†]
Sociodemographic			
Age (years), median (IQR)	39 (35 - 43)	59 (50 - 72)	<0.001
Parity, median (IQR)	2 (1 - 3)	2 (0 - 4)	0.38
Ethnic group			<0.001
Black	87 (97.8)	14 (58.3)	
White	2 (2.2)	9 (37.5)	
Indian	0	1 (4.2)	
Menopausal status			<0.001
Premenopausal	79 (88.8)	7 (29.2)	
Postmenopausal	10 (11.2)	17 (70.8)	
Tobacco use			0.15
Yes	2 (2.2)	2 (8.3)	
No	87 (97.8)	22 (91.7)	
Previous benign disease			0.39
Yes	18 (20.2)	3 (12.5)	
No	71 (79.8)	21 (87.5)	
Previous malignant disease			0.09
Yes	10 (11.2)	0	
No	79 (88.8)	24 (100)	
Comorbid disease			
Hypertension	11 (12.4)	11 (45.8)	<0.001
Controlled hypertension	10 (11.2)	10 (41.7)	0.002
Diabetes mellitus	3 (3.4)	3 (12.5)	0.08
Controlled diabetes mellitus	2 (2.2)	3 (12.5)	0.08
Other malignancy	2 (2.2)	2 (8.3)	0.6

IQR = interquartile range.

^{*}Except where otherwise indicated.[†]p-value from rank-sum, χ^2 or Fisher's exact test.**Table 2. Surgical procedures (N=113)**

Description	HIV positive (n=89), n (%)	HIV negative (n=24), n (%)	p-value [*]
Vulvectomy			0.23
Simple	23 (25.8)	3 (12.5)	
Radical	34 (38.2)	7 (29.2)	
Hemi-vulvectomy	10 (11.2)	5 (20.8)	
Wide local excision	22 (24.7)	9 (37.5)	
Inguinal lymphadenectomy			0.05
No	37 (41.6)	7 (29.2)	
Unilateral	3 (3.4)	4 (16.7)	
Bilateral	49 (55.1)	13 (54.2)	
Reconstruction flap			0.35
No	75 (84.3)	23 (95.8)	
V-Y	8 (9.0)	0	
Rhomboid	3 (3.4)	1 (4.2)	
Other	3 (3.4)	0	

^{*}p-value from χ^2 or Fisher's exact test.

count of 350 - 499 cells/ μ L (mild immunosuppression), 21 had a count of 200 - 349 cells/ μ L (advanced immunosuppression), and 24 had a count <200 cells/ μ L (severe immunosuppression). CD4 count data were missing for 1 patient.

There was no statistically significant difference between the HIV-positive and HIV-negative groups in the types of surgical procedure done for vulvectomy and reconstruction flaps. However, groin surgery for lymphadenectomy differed significantly between the groups, with more unilateral lymphadenectomies performed in the HIV-negative group ($n=4$; 16.7%) than in the HIV-positive group ($n=3$; 3.4%). A V-Y advancement flap was used in 8 patients (9.0%) in the HIV-positive group, but in no patient in the HIV-negative group.

The overall rates of complications after vulvar surgery were 33/89 (37.1%) and 5/24 (20.8%) in the HIV-positive and HIV-negative groups, respectively. The prevalence of complications was higher in the HIV-positive group, but not significantly so, with figures of 16/89 (18.0%) for sepsis, 14/89 (15.7%) for wound breakdown, and 1/89 (1.1%) each for flap necrosis and lymphocyst formation (Table 3).

Most bacterial cultures from vulvar wound swabs from the HIV-positive patients yielded non-commensal organisms. In descending order of prevalence, the organisms cultured in the HIV-positive group were *Pseudomonas aeruginosa*, *Proteus mirabilis*, and then *Morganella morganii*, *Klebsiella pneumoniae*, *Enterococcus faecium*, *Escherichia coli* and *Candida albicans*, with equal prevalences (Fig. 1). Four patients, all of whom were HIV positive, were infected by more than one organism; 1 patient had five organisms isolated and 3 patients had two organisms isolated. The two micro-organisms cultured in the HIV-negative group were Gram-negative commensals from the intestines/bowel.

There was a statistically significant association between the duration of hospitalisation and HIV status ($p=0.03$), with the median (interquartile range) duration in the HIV-positive group double that in the HIV-negative group (7 (3 - 11) days v. 3.5 (2 - 8) days, respectively). Table 4 shows additional results of associations between HIV status, wound healing and surgical outcomes.

Discussion

The International Society for the Study of Vulvovaginal Disease defines vulvectomy as removal of the entire or part of the vulva.^[2] Historically, *en bloc* vulvectomy was considered the gold standard, as it removes all malignant tissue including the skin bridging the groin and the vulva and provides longer life expectancy.^[3] However, the practice is no longer preferred owing to high rates of wound complications such as wound breakdown and infections.^[4] Clinicians therefore need to individualise the type of vulvectomy based on patient demographics, clinical characteristics and risk of wound complications.^[3,6] After vulvectomy, vulvar reconstructive procedures can be performed for cosmesis and improvement of sexual, urinary and defecatory function.^[3] Reconstructive techniques employed include skin grafts and skin flaps (local, regional and distant). These are associated with varying rates of wound complications such as infections, especially in women with comorbidities such as diabetes and HIV.^[7]

Surgery for vulvar cancer is associated with many early complications including wound dehiscence, wound infection, lymphocyst formation and haemorrhage.^[8] Late complications include chronic leg oedema, introital stenosis, and rectovaginal or rectoperineal fistulas. After surgery for

benign and/or premalignant lesions, wound breakdown is likely to occur in 30% of women, even with modified surgical techniques.^[9] Wound dehiscence and lymphoedema are the most common complications, with quoted rates of 20 - 40% and 30 - 70%, respectively.^[8,10]

Wound dehiscence and infection after vulvar surgery have been reported to occur most commonly after a mean period of 11 days.^[11] The extent of surgery, older age, diabetes mellitus, smoking, and previous radiotherapy on the vulva increase the risk of wound dehiscence.^[12,13] Preoperative patient preparation, sterile technique during surgery, and the use of prophylactic antibiotics have been shown to reduce the risk of postoperative infection and wound dehiscence.^[14]

A recent study reported a lack of association between preoperative risk factors (age/body mass index (BMI)) and the development of wound dehiscence.^[14] However, another study found that patients who were aged >65 years and obese (BMI >30 kg/m²) had a significantly higher risk of wound breakdown.^[15] Additional risk factors associated with wound breakdown include the number of lymph nodes resected, longer duration of surgery, and depth of tumour invasion. There was a significantly higher likelihood of wound dehiscence in patients with lymph node metastases following inguinofemoral lymphadenectomy. Postoperative complications also occurred more often with advanced tumour stages (FIGO (International Federation of Gynecology and Obstetrics) stages III and IV).^[14] One study found that wound infection was the most common short-term complication after vulvectomy for vulvar cancer,^[16] probably owing to the commensal flora on the vulva, the proximity of the anus, and challenges with maintaining good hygiene of the vulva after vulvectomy.^[9] Two studies showed that radical vulvectomy is a risk factor for post-vulvectomy wound infections.^[17,18]

It has been reported that in non-malignant lesions, the presence of high-grade vulvar dysplasia (as opposed to other non-premalignant lesions) increases the risk of infections.^[18] It was postulated that this is because dysplastic cells have suboptimal healing abilities. Other risk factors for wound infection in non-malignant lesions include greater specimen diameter and location of vulvar lesions on the perineum.

HIV increases the overall risk of surgical site infections in general surgical wounds.^[19] The present study showed that all complications were more common in the HIV-positive group, possibly as a result of immunocompromise and unhealthy, highly colonised vulvar skin associated with an altered immune system. Our postoperative wound complication rate of 33.6% was lower than the 42.3% reported in another study.^[18] The difference may be due to our small sample size. Recent studies have shown that once virological suppression is achieved, there is no difference in complication rates between HIV-positive and HIV-negative populations.^[20]

Culture showed some wounds in the HIV-positive group to have polymicrobial infections. Most organisms were sensitive to a similar group of drugs, but in two patients the organisms cultured were insensitive to these same drug groups. This finding suggests a need for multidrug antibiotic coverage. Our complication rates were higher than those reported in an Italian study of infections after genitourinary tract surgery, in which the surgical site infection rate was 14.3% in the HIV-positive group.^[21] This disparity may be due to differences in antiretroviral therapy coverage, degrees of immunosuppression, and perioperative infection control measures. The micro-organisms cultured were similar to those reported in an Indian study, in which *K. pneumoniae*, *P. aeruginosa* and

E. coli were the most common micro-organisms causing general surgical site infections in HIV-positive patient populations.^[22] A similar group of micro-organisms in post-vulvectomy wound sepsis was reported in a US study (*Enterococcus* species, *E. coli* and *P. aeruginosa*).^[11] Similarly, studies in Nigeria and Ethiopia reported that the most common organisms cultured in cases of wound breakdown were *S. aureus*, *K. pneumoniae*, *P. aeruginosa* and *E. coli*.^[23,24]

The present study showed that HIV-positive patients were more likely to undergo extensive surgery compared with those who were HIV negative. This difference is likely to be due to larger lesions that required extended excision borders to achieve negative margins. However, we did not assess

and compare the margin status in the two groups. It has been reported that the presence of high-grade vulvar dysplasia, greater specimen diameter and location of the lesion on the perineum were independent risk factors for overall postoperative vulvar wound complications.^[18] Although these authors did not report on the HIV status of their study population, it was noted that wound complications were most commonly experienced by immunocompromised patients: patients with diabetes, those on immunosuppressive drugs, and those with autoimmune diseases.

Vulvar pathologies were traditionally considered diseases of the elderly, with an increased incidence after the age of 60 years. With the advent of HIV, there was an increase in human papillomavirus-associated

Table 3. Complication rates and micro-organisms involved in sepsis (N=113)

Description	HIV positive (n=89), n (%)	HIV negative (n=24), n (%)	p-value*
Overall complication rate	33 (37.1)	5 (20.8)	0.15
Intraoperative complications			0.14
Unknown	0	1 (4.2)	
Nil	88 (98.9)	23 (95.8)	
Yes	1 (1.1)	0	
Specific postoperative complications			
Sepsis	16 (18.0)	3 (12.5)	0.52
Wound breakdown	14 (15.7)	1 (4.2)	0.13
Flap necrosis	1 (1.1)	1 (4.2)	0.32
Lymphocyst	1 (1.1)	0	0.60
Organism cultured†	16 (18.0)	3 (12.5)	0.52

*p-value from rank-sum, χ^2 or Fisher's exact test.

†See Fig. 1 for details of organisms cultured and Supplementary Table 1 (available online at <http://coding.samedical.org/file/2334>) for sensitivities.

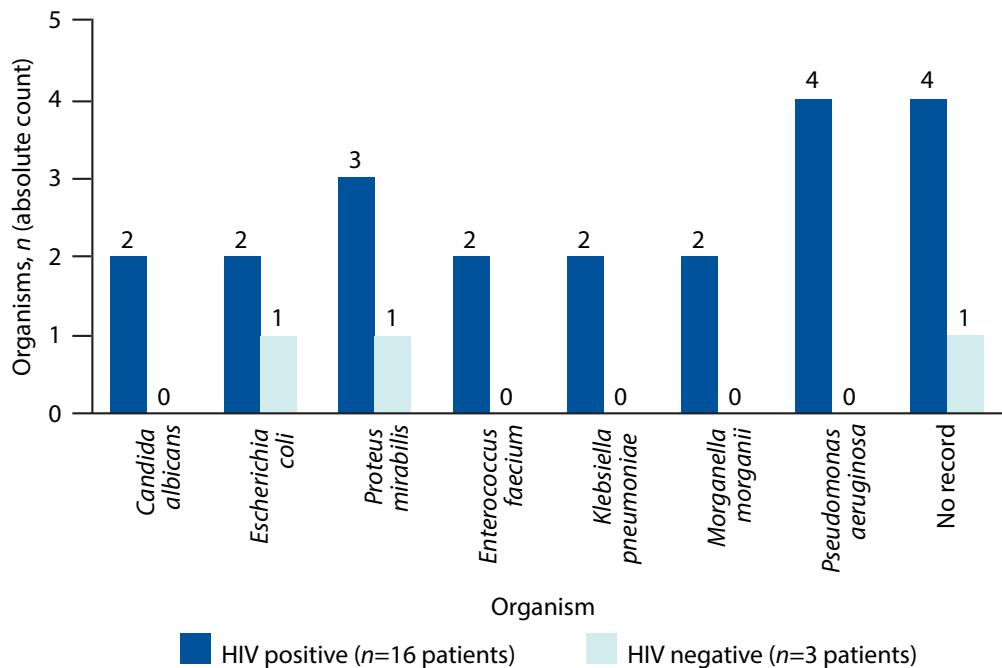


Fig. 1. Comparison of proportions of organisms cultured according to HIV status ($p=0.42$; Fisher's exact test). Some patients had more than one organism cultured. (No record = positive culture but no specific organism.)

Table 4. Association between HIV status, wound healing and surgical outcomes (N=113)

Description	HIV positive (n=89), n (%) [*]	HIV negative (n=24), n (%) [*]	p-value [*]
Surgical outcomes			
Duration of surgery (min), median (IQR)	60 (40 - 105)	53 (31 - 88)	0.13
Blood loss (mL), median (IQR)	0 (0 - 100)	0 (0 - 50)	0.21
Duration of hospitalisation (days), median (IQR)	7 (3 - 11)	3.5 (2 - 8)	0.03
Margin status			0.16
Free of disease	45 (50.6)	9 (37.5)	
Lichen sclerosus	2 (2.2)	0	
VIN	13 (14.6)	1 (4.2)	
Malignancy	10 (11.2)	5 (20.8)	
No data	18 (20.2)	9 (37.5)	
Other outcomes			
Recurrence	6 (6.7)	1 (4.2)	0.78
New pathology	1 (1.1)	0	0.60
Died	1 (1.1)	0	0.51

IQR = interquartile range; VIN = vulvar intraepithelial neoplasia.

^{*}p-value from rank-sum, χ^2 or Fisher's exact test.

vulvar lesions in women aged <40 years, including vulvar malignancies, especially in low- to middle-income countries.^[25] This is a possible explanation for the current findings that these diseases have a higher prevalence in premenopausal women.

Although this was not statistically significant, HIV-negative women in the present study were more likely than those who were HIV positive to undergo surgical procedures that were not extensive enough to require a reconstruction flap, but rather a primary repair.

Study limitations

The study was a secondary analysis of a previous study dataset, and it was therefore limited to the available data. The original study was a retrospective study, which by its nature has a number of limitations and biases. The findings of the study represent the cohort in one centre and cannot be generalised to another institution, district or regional population. Since this was a cross-sectional study, findings need to be interpreted with caution as the association does not necessarily imply causality. The sample size was small and possibly underpowered to determine significant differences between the HIV-positive and HIV-negative groups. However, despite these limitations, the study contributes valuable data to improve our local understanding of postoperative complications after vulvectomy among women living with HIV.

Conclusion

Vulvar lesions may warrant vulvectomy. However, vulvectomy is associated with multiple postoperative complications. In this study, these complications were most commonly observed in HIV-positive patients and resulted in longer hospitalisation than that for patients who were HIV negative. The overall complications observed were similar to what is recorded in the literature (wound breakdown, sepsis). In view of the micro-organisms most commonly identified, the choice of prophylactic

and empirical antibiotics administered pre- and postoperatively to patients undergoing vulvar surgery may need to be reviewed to improve successful treatment rates.

Declaration. The research for this study was done by the student team (TMK, DO, K-JR, MT, LK and SM) in partial fulfilment of the requirements for the MB BCh degree at the University of the Witwatersrand.

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Author contributions. LM conceptualised the study and supervised the research. VS was responsible for data collection. AC conducted data analysis and statistical interpretation. TMK served as the project leader, overseeing the workflow and performing final draft reviews. TMK, LK, DO, K-JR, MT and SM contributed to the literature review, document analysis and structuring of the manuscript. All authors reviewed and approved the final version of the manuscript.

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Data availability statement. The datasets generated and analysed during the current study are available from the corresponding author (TMK) upon reasonable request.

Conflicts of interest. None.

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