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Panzi score as a parsimonious indicator of urogenital fistula severity derived from Goh and Waaldijk classifications

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Synopsis: The Panzi score is presented as a single evidence-based score that is simple, comprehensive, and parsimonious, and will facilitate summative and predictive statistics.

Abstract

Objective: To derive a comprehensive system that allows a single score to define relative fistula severity.

Methods: The present observational study included women with urogenital fistula treated at the Panzi Hospital, Democratic Republic of Congo, or its outreach clinics across the Democratic Republic of Congo between September 1, 2013, and December 31, 2014. Fistula severity was assessed by Goh and Waaldijk classifications and surgical success was ascertained. Logistic regression was used to select fistula characteristics predictive of surgical failure, and to preliminarily verify the newly derived Panzi score.

Results: Overall, 837 women were included in the analysis. Goh or Waaldijk fistula descriptors associated with a higher probability of poor surgical outcomes in the unadjusted bivariate analysis were circumferential defect (P=0.007), proximity to the external urethral orifice (P=0.001), and size (P=0.001). These fistula characteristics were used to construct the Panzi score, which varied from 3 (most severe) to 0 (minor fistula). For each increase above 0, the odds of surgical failure increase by a factor of 1.65 (P<0.001).

Conclusion: The Panzi score of urogenital fistula provided a data-driven, simple, comprehensive, and parsimonious score. It could be used to report group data, to provide continuous level data for use in higher order statistics, and to resolve issues such as the cut-off point for referring women to hospital in accordance with fistula complexity.

1 INTRODUCTION

There are more than 2 million cases of genital fistula in Sub-Saharan Africa and Asia [1]. Urogenital fistulas, abnormal openings between the vagina and bladder or urethra, are characterized by constant leakage of urine from the vagina. Different descriptive classification systems exist for urogenital fistula [2] but none has been internationally agreed [3–5] or provides a single composite score.

The most commonly used urogenital classification systems are those of Waaldijk [6] and Goh [7]. Despite extensive overlap, and owing to the strengths and weaknesses of both systems, many clinical sites use both Goh and Waaldijk classifications simultaneously in an attempt to document fistula characteristics and severity comprehensively.

The primary aim of the present study was to determine the individual components of the Goh and Waaldijk classification systems that were prognostic of surgical outcome to derive a single evidence-based score for urogenital fistula that was clear, simple, comprehensive, and parsimonious. A secondary aim was to compare this "Panzi score" to published urogenital fistula classifications to identify key components that could have been missed.

2 MATERIALS AND METHODS

The present observational study was conducted among women treated for urogenital fistula within the Panzi Hospital Health System, including the referral hospital and its outpatient clinics throughout the Democratic Republic of Congo, between September 1, 2013, and December 31, 2014. Ethical approval for the present study was received from the Institutional Ethics Committee of the Catholic University of Bukavu, Democratic Republic of the Congo, (UCB/CIE/NC/10/2013) and approval for the analysis of the de-identified data was confirmed at the University of Michigan, Ann Arbor, USA (HUM00140194). All participants received and signed informed consent documents.

For each woman treated for fistula during the study period, fistula characteristics were documented using both the Waaldijk and the Goh classifications systems. Patients were

excluded from the present analysis if information on surgical outcome or components of the Goh or Waaldijk classifications were missing, or if the fistula was classified as "Waaldijk type III" or "Goh fibrosis special consideration" because these miscellaneous categories do not provide information specific to urogenital fistula.

Demographic, gynecologic, obstetric, surgical, and fistula-specific data, including Goh and Waaldijk classification, were expressed as mean±SD or as absolute numbers with percentages. Logistic regression models were used to determine associations between fistula classifications and probability of surgical failure, defined using urine leakage status at approximately 2 weeks after surgery. The outcome variable was collected as successful (dry), urge incontinence (wet), stress incontinence (wet), or failure (wet); however, all three "wet" categories were grouped into a single category, "failure" for analysis.

Individual models for the Waaldijk classification system and each component of the Goh classification system were built to determine unadjusted associations. A multivariable model adjusting for significant components of both classification systems was then built to determine adjusted associations. For each component of Goh and Waaldijk, pairwise comparisons were made to determine whether categories of the component had statistically similar effects on surgical outcomes and could be grouped together. The results from these models were used to develop the Panzi score.

The clinical data used to analyze the Waaldijk and Goh systems were also applied to a logistic regression to determine the association between the proposed Panzi score (both as continuous and categorical variable) and the probability of surgical failure. Logarithmic odds ratios from this model were plotted as a visual representation of this association. All data analyses were conducted by using SAS version 9.4 (SAS Institute, Cary, NC, USA) and $P<0.05$ was considered statistically significant.

3 RESULTS

During the study period, 1219 women were treated for fistula. Of these, 382 (31.3%) were excluded; 319 (26.2%) owing to missing information on surgical outcome or one of the classification systems and 63 (5.2%) owing to being classified as “miscellaneous” by one of the classification systems.

The 837 women included in the analysis had a mean age of 32.18±12.17 years, height of 150.26±8.79 cm, 2.65 previous vaginal deliveries, and 1.51 live children (Table 1). The average age at first delivery was 18.05±4.22 years, and the average age at fistula occurrence was 18.38±10.57 years. The majority of fistulas occurred after delivering, with smaller proportions occurring after sexual violence or surgical adverse events, and the remainder having resulted from “other events” or “unknown” causes. The 382 patients excluded from the analysis differed from those included in education level, religion, event after which fistula symptoms began, place of delivery when symptoms first occurred, number of vaginal deliveries, and number of live deliveries (all $P<0.05$; data not shown). Surgical success (dry outcome) was achieved for 741 (88.5%) patients.

Most fistulas were classified by the Waaldijk classification system as lacking involvement with the closing mechanism (type I, 616 [73.6%]); the remainder with involvement were classified as having subtotal involvement (type IIA, 172 [20.5%]), and total involvement (type IIB, 49 [5.9%]) (Table 2). In this classification, fistulas that involved a circumferential defect (i.e., type II Ab or Bb from Waaldijk classification) were 2.41 times more likely to result in surgical failure compared with fistulas that did not involve a circumferential defect in the unadjusted analysis ($P=0.007$) (Table 3).

Using the Goh classification, 410 (49.0%) fistulas were classified as type 1, and only 54 (6.5%) were classified as type 4 (Table 2). In the unadjusted analysis, Goh fistula type was significantly associated with probability of surgical failure ($P=0.001$), and type 4 was associated with the highest odds of failure compared with type 1 (odds ratio [OR] 3.26; $P=0.002$) (Table 3). Type 3 also demonstrated significantly increased odds of surgical failure compared with type 1 (OR 2.15; $P=0.010$); however, type 2 did not ($P=0.074$).

Additionally, type 3 and type 4 had similar odds of surgical failure when compared (*P*=0.297). Consequently, types 1 and 2, and types 3 and 4 were grouped together to form a two-category measure of location; these were described as close to the external urethral orifice (EUO) (<2.5 cm, i.e., types 1 and 2), and far from the EUO (≥2.5 cm, i.e., types 3 and 4).

The Goh classification included the diameter of the fistula, which was also associated with surgical failure; in the unadjusted analysis, larger fistulas (>3 cm) were associated with 2.41-fold higher odds of surgical failure compared with the smallest fistulas (<1.5 cm; *P*=0.003) (Table 3). Fistulas 1.5–3 cm in diameter were not associated in any increase in the odds of surgical failure compared with the smallest fistulas; therefore, these categories were combined such that the proposed categorization of fistula size was large (>3 cm) and small (≤3 cm).

Goh fibrosis classification (moderate/severe versus none/mild) was not significantly associated with surgical failure (Table 3). The direction of the parameter estimate was higher odds of surgical failure for moderate/severe fibrosis compared to none/mild fibrosis.

A multivariable model predicting the probability of surgical failure from the refined categories described above and the components of the Waaldijk and Goh classifications that were associated with surgical outcomes indicated that, after adjusting for other characteristics, larger fistulas (>3 cm) were associated with significantly higher odds of surgical failure (OR, 1.94, 95% confidence interval 1.12–3.36; *P*=0.018) (Table 4). The classification of a fistula being close to the EUO (<2.5 cm) was marginally associated with a higher probability of surgical failure (OR=1.64, 95% CI=0.99-2.69, *P*=0.053). The presence of circumferential defect was also not significantly associated with surgical failure; again, a numerically higher probability of surgical failure was recorded (*P*=0.400). Additionally, no significant interactions among the fistula characteristics were detected. In addition, no differences between parameter estimates for the three fistula characteristics were detected, therefore, other characteristics being equal, each fistula

characteristic (location, size, circumferential defect) has an approximately equal effect on the probability of surgical failure in the current sample.

On the basis of the multivariable analysis, the Panzi score for urogenital fistula was constructed with three subcomponents: location, size, and circumferential defect. In this classification, each component is given a score of 1 if the fistula exhibits the most severe form of each characteristic (i.e., <2.5 cm from EUO, circumferential defect, and >3 cm in size), and 0 otherwise. Adding the scores provided the total Panzi score for severity, ranging from 0 to 3. A Panzi score of 0 represented a low-severity fistula, characterized by Waaldijk as type I, type IIAa, or type IIBa (no circumferential defect), and characterized by Goh as type 1 or 2 (far from EUO, and <1.5 cm or 1.5–3.0 cm in diameter). A score of 1 described fistulas that were severe in only one category, and can be mapped to either a Waaldijk type II Ab or Bb (circumferential defect), Goh type 3 or 4 (close to EUO), or Goh size bigger than 3 cm. Scores of 2 or 3 represent fistulas with a combination of two or all three of the more severe characteristics, respectively.

The Panzi score was subsequently calculated for each of the 837 study participants. Women with higher scores were found to have a higher proportion of surgical failure; the highest incidence of surgical failure was observed for women with a fistula with a Panzi score of 3 (Table 5). The Panzi score as a continuous variable was significantly associated with increased odds of surgical failure (P<0.001), with each 1-point increase in Panzi score associated with a 65% increase in the odds of surgical failure, and higher scores (indicative of greater severity) were associated with a higher odds of surgical failure as compared with a Panzi score of 0 (Table 5) (Figure 1).

4 DISCUSSION

Goh and Waaldijk, the most common fistula classifications [5], are often used simultaneously due to the strengths and weakness of each. By examining the associations between various components of Goh and Waaldijk and surgical outcome, the present study demonstrated that both Goh and Waaldijk have elements that are prognostic of surgical outcomes; however, each has components that lack clarity and

neither was found to be sufficiently comprehensive. The Panzi score was therefore derived to provide a simple and comprehensive score for urogenital fistula, representing a useful indicator for clinical work. It provides a single digit "score," which separates it from other classification systems that rely on complex descriptive information that cannot be easily reduced to a numerical value for use in reporting statistics, grouping data, and model testing for predictive value. The Panzi score yields a single ordered score across four levels (total score of 0, 1, 2, or 3), and has the potential for robust statistical analysis in future research studies. Notably, this scoring system focuses on only urogenital fistula, it eliminates overlap and redundancy, it uses precise, intuitive language, and it clarifies ambiguities. It provides both a method to report both descriptive and categoric scoring across three fistula components, and a single, summative score to indicate overall severity and/or complexity (ranging from 0 to 3).

On the basis of clinical input, we hypothesized that presence of fibrosis, a characteristic within the Goh classification system, would have a significant impact on the probability of surgical failure. However, this hypothesis was not proven in the current study sample, and fibrosis severity was therefore not included in the proposed Panzi score. The lack of statistical significance in the multivariate analysis could possibly be due to a lack of power (96 [11.5%] surgical failures among 837 women). However, we continue to hypothesize that fistulas with severe fibrosis have higher rates of repair failure. As a sensitivity analysis, therefore, the Goh fibrosis measure was included in the multivariable model: the odds ratios for the other three characteristics were similar to those in the model without fibrosis and all parameter estimates remained approximately equal (Table 4).

The components of the Panzi score were compared with those of other classifications, including Goh and Waaldijk (Table 6). The Panzi score matches the comprehensive classification system of Tafesse [8], which includes the three components of the Panzi score. Components found in other classifications but not in the Panzi score or the Tafesse classification system include "scarring" or "fibrosis" and anecdotal comments of "previous repair" or "shortened vaginal length" that are sometimes used as a proxy for

fibrosis. The Tafesse classification system differs from the Panzi score in that, as per the goals of all classification systems, it is descriptive across the components and not readily reducible to a single numerical “score.”

The Panzi score provides a consolidated classification that can solve existing problems and provide a foundation for answering additional research questions such as determining a cutoff score for women who need a specialty referral center. The present investigation into fistula characteristics that are associated with surgical outcome did not find differences in magnitude of association; therefore, in the interest of developing a parsimonious tool that could be easily implemented in more remote clinical settings, all characteristics were given equal weight. The initial finding that critical components were not overlooked was confirmed by the comparison with published urogenital classification systems. Further validation of the score, including whether equal weighting is appropriate, is ongoing.

The study had some limitations. First, the study outcome “wet” versus “dry” was general and not limited to unsuccessful closure of the fistula, as shown in a previous study where 16% of patients with a surgically closed fistula experienced incontinence after the repair [9]. However, the wet versus dry outcome was the measure most in line with patient satisfaction. Persistence of stress and urge incontinence after surgery could imply residual effects from fistula severity and could be associated with significant lesions to the closure mechanism and with the size of the fistula. If non-fistula-related incontinence is assumed to add “noise” to the outcome variable of wet versus dry, then it will be harder to detect a confirmatory signal to validate the Panzi score; consequently, it could be argued that the present findings are conservative.

Second, the inclusion criteria resulted in the exclusion of 382 women from the overall sample of 1219. The excluded women differed from the included women in several demographic and obstetric characteristics; further exploration of these factors is suggested but was beyond the scope of the present study. Third, there was a low number of surgical failures on which to base the analysis, although the percentage of

success in the study (88.5%) was similar to previously reported values (87%–93%) [9-11]. The equal weights assigned to each fistula characteristic should be validated in a larger sample.

Contrary to previous studies [9, 11] and the expert opinion of physicians at Panzi Hospital, the data showed no association between fibrosis severity and probability of surgical failure. It is speculated that the limitations of the data set, based on Goh and Waaldijk classifications, made it difficult to clearly distinguish between meaningful levels of fibrosis, and that the current data were not reflective of the latent severity levels. The Goh system includes categories for fibrosis, but the two categories are subjective and not pure because “none” and “mild” fibrosis are considered as one choice, and “moderate” and “severe” are considered as one choice. Consequently, there is both a lack of distinction and a potential for high rates of misclassification. Further work is needed to clearly define meaningful categories of fibrosis and explore how it should be incorporated into the proposed scoring system. Therefore, a separate section made of three columns was attached to the proposed form for determining the Panzi score (Box 1) to improve its descriptive capability, to allow further data collection on vaginal fibrosis (subjective), and to assess the relationship between fibrosis and patient vaginal length (more objective) and prior surgical attempts at repair (known to be associated with fibrosis). Further physician observations can be collected in the “Notes” row, enabling the Panzi score to be refined further over time.

The present study should not be misconstrued as a definitive validation of the Panzi score. Validation requires new sampling, whereby data are collected directly via the Panzi scoring system rather than derived from Goh and Waaldijk variables. The Panzi score for urogenital fistula is presented here as a first step toward full validation of a single evidence-based score of urogenital fistula that is simple, comprehensive, and parsimonious.

Author contributions

All authors contributed to the design of the study, the collection, analysis, and interpretation of data, and writing and revising the manuscript. All authors approved the final manuscript.

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Conflicts of interest

The authors have no conflicts of interest.

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Figure 1 Probability of surgical failure with increasing Panzi score. The logarithm of the odds ratio is plotted. The reference category was a score of 0; 95% confidence bars are shown.

Table 1 Characteristics of the 837 study women. [a]

Characteristic	No. of women with data available	Value [a]
Demographic		
Age, y	755	32.18 ± 12.17 (12–80)
Height, cm	746	150.26 ± 8.79 (123–180)
Weight, kg	772	48.64 ± 7.57 (30–80)
Marital status	817	
Married		493 (60.3)
Single		54 (6.6)
Divorced		211 (25.8)
Widowed		59 (7.2)
Education level	817	
None		370 (45.3)
Primary		360 (44.1)
At least secondary		87 (10.6)
Profession	806	
Farmer		619 (76.8)
Housewife		131 (16.3)
Other		56 (6.9)
Clinical		
Never pregnant	821	5 (0.6)
No. of pregnancies	806	3.63 ± 3.04 (0–22)
No. of vaginal deliveries	788	2.65 ± 2.73 (0–16)
No. of cesarean deliveries	778	0.67 ± 0.77 (0–6)
No. of days in labor	741	2.57 ± 2.50 (0–48)
No. of days in labor before seeking care at healthcare facility	650	2.01 ± 1.81 (0–21)
When did symptoms begin?	804	
After delivery		718 (89.3)
After sexual violence		11 (1.4)

Characteristic	No. of women with data available	Value [a]
After surgical adverse event		15 (1.9)
After other event or unknown		60 (7.5)

[a] Overall, 1219 women were treated for fistula during the study period; 382 were excluded owing to missing data on surgical outcome or classification variables, or because the fistula could not be classified as vesicovaginal.

[b] Values are given as mean ± SD (range) or number (percentage).

Table 2 Stratification of patients using Waaldijk and Goh classifications (n=837). [a]

Feature	Waaldijk classification		Goh classification	
	Description	No. (%)	Description	No. (%)
Fistula location	≥5 cm from EUO (type I)	616 (73.6)	>3.5 cm from EUO (type 1)	410 (49.0)
	<5 cm from EUO (type II)	221 (26.4)	2.5–3.5 cm from EUO (type 2)	234 (28.0)
			1.5 to <2.5 cm from EUO (type 3)	139 (16.6)
			<1.5 cm from EUO (type 4)	54 (6.5)
Fistula size	NA		<1.5 cm	325 (38.8)
	NA		1.5–3 cm	392 (46.8)
	NA		>3 cm	120 (14.3)
Circumferential defect	Yes (types IIAb and IIBb)	63 (7.5)	NA	
	No (types IIAa and IIBa)	774 (92.5)	NA	
Fibrosis	NA		None/mild	653 (78.0)
	NA		Moderate/severe	184 (22.0)

Abbreviations: EUO, external urethral orifice; NA, not applicable.

[a] In Waaldijk classification, type I refers to fistulas located at least 5 cm from the EUO and therefore without involvement of the urethral closing mechanism. In Goh, type I refers to a fistula with a distal edge more than 3.5 cm from the EUO, and thus is a cutoff point closer to the urethral closing mechanism as compared with Waaldijk type I. Only Waaldijk provides an indicator of whether the fistula has crossed the urethra completely or only partially (circumferential defect). Only Goh considers the size of the fistula. Waaldijk does not consider fibrosis, whereas Goh uses four descriptive categories combined in a dichotomous variable (none/mild or moderate/severe [6,7].

Table 3 Associations between probability of surgical failure and fistula characteristics based on Goh and Waaldijk categories (bivariate unadjusted model).

Fistula characteristic	Odds ratio (95% confidence interval)	*P* value
Location		0.001
>3.5 cm from EUO	Ref.	
2.5–3.5 cm from EUO	1.62 (0.95–2.74)	0.074
1.5 to <2.5 cm from EUO	2.15 (1.21–3.83)	0.010
<1.5 cm from EUO	3.26 (1.57–6.80)	0.002
Size		0.001
<1.5 cm	Ref.	
1.5-3 cm	1.01 (0.62–1.66)	0.963
>3 cm	2.41 (1.36–4.27)	0.003
Circumferential (yes vs no)	2.41 (1.28–4.56)	0.007
Fibrosis (moderate/severe vs none/mild)	1.21 (0.74–1.98)	0.449

Abbreviation: EUO, external urethral orifice.

Table 4 Associations between probability of surgical failure and fistula characteristics based on reduced categories of characteristics (multivariable adjusted model).

Fistula characteristic	Final model		Sensitivity analysis including fibrosis	
	OR (95% CI)	*P* value	OR (95% CI)	*P* value
Location (<2.5 cm vs ≥2.5 cm from EUO [ref.])	1.64 (0.99–2.69)	0.053	1.63 (0.99–2.69)	0.056
Size (>3 cm vs ≤3 cm [ref.])	1.94 (1.12–3.36)	0.018	1.93 (1.11–3.37)	0.020
Circumferential (yes vs no [ref.])	1.37 (0.66–2.86)	0.400	1.37 (0.66–2.86)	0.398
Fibrosis (moderate/severe vs none/mild [ref.])			1.03 (0.06–1.71)	0.914

Abbreviations: CI, confidence interval; EUO, external urethral orifice; OR, odds ratio.

Table 5 Association between proposed Panzi score and odds of surgical failure (n=837).

Panzi score	Surgical failure [a]	Odds ratio (95% CI)	*P* value
Continuous		1.65 (1.30–2.09)	<0.001
0	50/566 (8.8)	Ref.	
1	27/194 (13.9)	1.67 (1.01–2.75)	0.045
2	11/49 (22.4)	2.99 (1.44–6.21)	0.003
3	8/28 (28.6)	4.13 (1.73–9.85)	0.001
Overall			0.006 [b]

[a] Values are given as number of surgical failures/number of patients assigned Panzi score (percentage).

[b] Overall *P* value for categorical score.

Table 6 Comparison of Panzi score with existing classifications of urogenital fistulas.

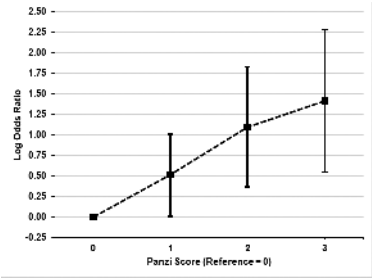
Classification system	Characteristics included in classification					
	Location	Size	Circumference	Scarring/ fibrosis	Vaginal length	Previous repair
Sims [12]	Yes					
Mahfouz [13]	Yes					
Moir [14]	Yes		Yes			
McConnachie [15]	Yes	Yes		Yes		
Bird [16]	Yes		Yes			
Lawson [17]	Yes	Yes				
Gray [18]	Yes	Yes		Yes		
Hamlin and Nicholson [19]	Yes					
Waaldijk [6]	Yes		Yes			
Goh [7]	Yes	Yes		Yes		Yes
Arrowsmith [2]			Yes	Yes		Yes
Tafesse [8]	Yes	Yes	Yes			
Panzi score	Yes (*P*=0.001)	Yes (*P*=0.010)	Yes (*P*=0.007)	No (*P*=0.449) [a]	Not tested	Not tested

[a] Not statistically significant in the present analysis; therefore, not included in the Panzi score.

Box 1 Proposed Panzi urogenital scoring system, including space to document additional potentially clinically important indicators of fistula complexity

Characteristic	Score	Fibrosis/ scarring grade	Vaginal length, cm	No. of previous repair

		attempts
Distance of distal edge of fistula from external urethral orifice (≥2.5 cm = 0; <2.5 cm = 1)	0–1	None = A Mild = B
Size of fistula (≤3 cm = 0; >3 cm = 1)	0–1	Moderate = C
Circumferential (no = 0; yes = 1)	0–1	Severe = D
Panzi score (summed total)	0–3	
ADDITIONAL NOTES (e.g., presence of multiple fistula, incontinence prior to fistula, etc.)		



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