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Predictors of successful outcome of tubularized incised plate for primary distal hypospadias repair

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Abstract

Background: Several preoperative factors affect the outcome of Tabularized Incised Plate (TIP) repair. Our aim was to collect and analyze all these factors to define what the most important predictive factors are.

Methods: Hundred patients (1–5 years old) with primary distal hypospadias were included. Exclusion criteria included previous penile operations and hormonal treatment or associated congenital anomalies. Anogenital distance (AGD), stretched penile length (SPL), meatal site, glanular shape, chordee and torsion degree, plate width and glans meatus shaft (GMS) score were assessed. TIP repair was done to all patients and followed up for one year. The outcome was correlated with the above parameters.

Results: Mean ± SD of age of patients was 3.5 ± 1.5 years, while weight was 14.1 ± 3.0 kg. Complication rate was 18% including urethrocutaneous fistula (UCF) and meatal stenosis 14%, repair breakdown 1% and urethral stricture 3%. Patients with chordee degree < 30° and distal penile meatal location were associated with increased risk for complications by 11.6 and 8.2 times; 95% CI was (1.46–91.75) and (1.02–66.52), respectively ($p < 0.05$ for each). Plate width ≥ 9 mm, AGD > 5 cm, GMS score ≤ 7 ($p < 0.001$ for each), age of patient ≤ 2 years old, and SPL > 3.5 cm ($p < 0.01$ for each) were associated with successful outcome of repair.

Conclusion: The proposed successful criteria of TIP repair were absent chordee, coronal/subcoronal penile meatal location, plate width ≥ 9 mm, AGD > 5 cm, age of patient ≤ 2 years old, GMS score ≤ 7, SPL > 3.5 cm and grooved glanular shape.

Keywords: Hypospadias, TIP repair, Predictors, Outcome

1 Background

Hypospadias is the most common penile congenital malformation characterized by abnormal positioning of the urethral opening due to abnormal embryological development of the urethral fold and the ventral foreskin of the penis [1].

Although hypospadias incidence is 1 to 300 live births, hypospadias surgery is not considered routine daily work surgery because it is considered as reconstructive surgery and needs more experience to deal with. Hundreds of surgical techniques of hypospadias repair had been described with no single procedure dedicated as the gold standard for repair. Many techniques and modifications were developed to enhance the outcome of surgery [2].

Snodgrass has described tubularized incised plate urethroplasty in 1994 and since that time, it became the most popular technique for repair of distal penile hypospadias and some forms of proximal hypospadias [3].

The main concern in all hypospadias surgeries is to get the penis straight with a slit-like orthotopic meatus for

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good urine outflow with good cosmoses for child self-satisfaction later on his life [4].

Many modifications had been made to enhance the TIP technique outcome [5]. Despite all precautions, the complications such as meatal stenosis and fistula formation can develop indicating the importance of the structural alteration in hypospadias patients and anatomical preoperative factors such as anogenital distance, meatal site, glanular shape, chordee degree, plate width and GMS score [5].

The aim of our study is to analyze the preoperative anatomical factors that could affect the outcome of primary TIP repair for distal hypospadias.

2 Methods

This prospective cohort study included one hundred and nine patients (1–5 years old) with TIP repair for primary distal hypospadias. All patient's caregivers signed informed consent according to the principles embodied in the Declaration of Helsinki (https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/) for all investigations involving human materials and approved by Suez Canal University ethical committee under number 4071/2020. Four patients refused to participate and five patients were lost follow-up and excluded from the study. The study was carried out at the urology department, Suez Canal University Hospital.

Sample size was calculated as 100 patients based on 70% overall success rate (as reported by Mohajerzadeh et al. [6]), and 9% absolute precision rate (using Openepi online calculator available at https://www.openepi.com/SampleSize/SSPropor.htm). An 8% of the calculated sample size was added to compensate for dropout giving a final sample size of 109 [6].

Each patient was assessed by history and genital examination preoperatively including age, weight, meatal site from coronal to distal penile location, glanular shape (cleft or grooved), chordee degree (absent, < 30°), penile torsion degree (absent, < 30°) and urethral plate width in mm.

SPL in cm was measured from the tip of glans to the base of penis in the supine position using a ruler. AGD in centimeters was measured from mid anus to the base of scrotum in frog-leg position using a ruler by the same senior surgeon.

GMS score was based on anatomic features where the G score for the assessment of the glans shape, and urethral plate width, the M score for meatal site and the S score for penile shaft chordee. Each of the three components was scored numerically on a scale of 1–4 with more unfavorable characteristics being assigned higher values. These values are then summed to calculate the GMS total score. The lowest score is 3, and the highest is 12. Patients were classified into three categories: mild (GMS 3–6), moderate (GMS 7–9) and severe hypospadias (GMS 10–12) [7].

Our exclusion criteria included patients with history of penile operations and hormonal treatment (local testosterone or HCG injections) or associated other congenital anomalies such as cryptorchidism.

The same surgeons without experience difference that could affect the outcome did TIP repair for all patients using vicryl 6/0 round needle interrupted tubularization suture, vicryl 5/0 round needle mattress glanuloplasty suture and second dartos layer coverage.

All cases had 10 days of urethral catheterization (8 or 10 Fr), 5 days of simple non-compressive dressing and antibiotic therapy until catheter removal.

All patients were followed up and examined after one week for only repair breakdown by inspection. In addition, after removal of urethral catheter at 1 month, 6 months and 1 year for the presence of UCF and repair breakdown by inspection, meatal stenosis or stricture urethra by calibration with tip of thermometer and nelaton catheter 8 French, respectively and uroflowmetry and urethrogram in toilet trained boys. On follow-up evaluation, caregivers were asked about the caliber and quality of urine stream and the presence of any voiding straining. All the included patients completed at least 1-year period of postoperative follow up.

2.1 Data analysis

The Statistical Package performed all data manipulation and statistical analyses for the Social Sciences (SPSS version 25.0; IBM Corporation, Armonk, NY, the USA). Univariate analysis of the study population was expressed as frequencies and percentages (%) or mean and standard deviations (SDs). Bivariate analysis between frequencies in the studied groups was assessed by chi-square test or Fisher's exact test (if > 20% of expected values were less than 5). Continuous variables were not normally distributed, and Mann–Whitney test was used to assess differences of these variables distributions between the studied groups.

Multivariate analysis was performed using backward stepwise logistic regression. In this regression model, all variables were entered on the first step (age, SPL, AGD, GMS, plate width, meatal site, chordee degree, and torsion degree). Weight was excluded because it was highly insignificant in the univariate analysis, while glandular shape was excluded because its grooved category had insufficient number of cases.

Regression coefficients and its standard errors, as well as odds ratios (OR) and its 95% confidence intervals for the predictors (only remained on the last step), were presented in the multivariate analysis table. A p value < 0.05

was considered statistically significant. Receiving operating characteristic (ROC) curve was used to detect cut-off value of the continuous variables.

3 Results

Mean ± SD of all continuous variables was presented as patient's age 3.5 ± 1.5 years, weight 14.1 ± 3.0 kg, SPL 3.8 ± 0.9 cm, AGD 5.2 ± 1.4 cm, GMS score 6.3 ± 1.7 and plate width 9.8 ± 1.6 mm. Meatal site was classified as coronal, subcoronal, and distal penile as 10%, 29%, and 61%, respectively. Glanular shape was cleft in 58% and grooved in 42%. Chordee degree was absent in 41% of patients and < 30° in 59%. Torsion degree was absent in 63% and < 30° in 37% of patients. The overall complication rate was 18%; UCF and meatal stenosis were 14%, repair breakdown was 1%, and urethral stricture was 3% (Table 1).

Mean ± SD of age in complicated versus uncomplicated cases was (4.3 ± 1.0 vs. 3.3 ± 1.6 years), SPL (3.3 ± 0.8 vs. 3.9 ± 0.9 cm) ($p < 0.01$ for each). Mean ± SD of AGD in complicated versus uncomplicated cases was (3.9 ± 1.0 vs. 5.4 ± 1.4 cm), GMS score (8.3 ± 0.8 vs. 5.9 ± 1.6), plate width (8.3 ± 0.5 vs. 10.1 ± 1.7 mm) ($p < 0.001$ for each). The percentage of distal penile meatal location versus coronal/ subcoronal in complicated cases was (83.3% vs. 16.7%), mild clefted glanular shape versus grooved (88.9% vs. 11.1%), chordee degree < 30° versus absent chordee (83.3% vs. 16.7%) ($p < 0.05$ for each) (Table 2).

Both patient's Mean ± SD of weight in kg and the percentage of torsion degree were not statistically significant regarding correlation to the outcome of repair ($p = 0.828$ and $= 0.072$) respectively (Table 2).

The likelihood of complications was increased by 4 times with every year increase in patient's age (95% CI 1.554–10.357, $p < 0.01$). Patients with distal penile meatal location were 8.2 times more likely to develop complications after surgical repair, compared to coronal or subcoronal meatal site (95% CI 1.020–66.520, $p < 0.05$). Patients with chordee degree < 30° were 11.6 times more likely for developing complications after surgical repair compared to absent chordee (95% CI 1.468–91.757, $p < 0.05$). On the other hand, the one-unit increase in AGD (95% CI 0.148–0.996, $p < 0.05$) and plate width (95% CI 0.068–0.869, $p < 0.05$) was associated with 62% and

Table 1 Demographic data of studied patients ($N = 100$)

Parameters	Mean ± SD or no. (%)
Age (years)	3.5 ± 1.5
Weight (kg)	14.1 ± 3.0
SPL (cm)	3.8 ± 0.9
AGD (cm)	5.2 ± 1.4
GMS score	6.3 ± 1.7
Plate width (mm)	9.8 ± 1.6
Meatal site	
Coronal	10 (10.0%)
Subcoronal	29 (29.0%)
Distal penile	61 (61.0%)
Glanular shape	
Grooved	42 (42.0%)
Mild clefted	58 (58.0%)
Chordee degree	
Absent	41 (41.0%)
< 30	59 (59.0%)
Torsion degree	
Absent	63 (63.0%)
< 30	37 (37.0%)
Outcome of repair	
Healed	82 (82.0%)
UCF and meatal stenosis	14 (14.0%)
Repair breakdown	1 (1.0%)
Urethral stricture	3 (3.0%)

SD standard deviation, *Kg* kilograms, *Cm* centimeter, *mm* millimeter, *AGD* anogenital distance, *GMS* glans meatus shaft, *SPL* stretched penile length, *UCF* urethrocutaneous fistula

Table 2 Relation between the studied factors and the outcome of TIP repair ($N = 100$)

Variables	Uncomplicated $n = 82$	Complicated $n = 18$	*p* value
Age (years)	3.3 ± 1.6	4.3 ± 1.0	0.001*[a]
Weight (kg)	14.0 ± 3.1	14.2 ± 2.7	0.828[a]
SPL (cm)	3.9 ± 0.9	3.3 ± 0.8	0.006*[a]
AGD (cm)	5.4 ± 1.4	3.9 ± 1.0	< 0.001*[a]
GMS score	5.9 ± 1.6	8.3 ± 0.8	< 0.001*[a]
Plate width (mm)	10.1 ± 1.7	8.3 ± 0.5	< 0.001*[a]
Meatal site			
Coronal/subcoronal	36 (43.9%)	3 (16.7%)	0.032*[c]
Distal penile	46 (56.1%)	15 (83.3%)	
Glanular shape			
Grooved	40 (48.8%)	2 (11.1%)	0.003*[c]
Mild clefted	42 (51.2%)	16 (88.9%)	
Chordee degree			
Absent	38 (46.3%)	3 (16.7%)	0.020 *[c]
< 30	44 (53.7%)	15 (83.3%)	
Torsion degree			
Absent	55 (67.1%)	8 (44.4%)	0.072[c]
< 30	27 (32.9%)	10 (55.6%)	

Kg kilograms, *cm* centimeter, *mm* millimeter, *AGD* anogenital distance, *GMS* glans meatus shaft, *SPL* stretched penile length, *TIP* tubularized incised plate

*Statistically significant at $p < 0.05$

[a] Independent samples *T* test

[b] Fischer's exact test

[c] Chi-square test

Table 3 Multivariate analysis for the predictors of complicated TIP repair among the studied patients ($N=100$)

Predictors	B	SE	*p* value	Odds ratio (OR)	95% CI for OR	
					LL	UL
Age (years)	1.389	0.484	0.004*	4.012	1.554	10.357
AGD (cm)	−0.957	0.486	0.049*	0.384	0.148	0.996
Plate width (cm)	−1.412	0.649	0.029*	0.244	0.068	0.869
Meatal site (distal penile)	2.109	1.066	0.048*	8.239	1.020	66.520
Chordee degree (< 30)	2.451	1.055	0.020*	11.604	1.468	91.757
Constant	4.647	5.416	0.391	104.323		

*Statistically significant *p* value at $p<0.05$ (backward stepwise logistic regression)

[a] Model Characteristics: Chi-square = 57.78 (*p* value < 0.001); Correct Class % = 91%; Hosmer and Lemeshow test = 0.567; Negelkerke *R* square = 0.72

β regression coefficient; *TIP* tubularized incised plate, *SE* standard error, *Cm* centimeter, *mm* millimeter, *AGD* anogenital distance, *CI* confidence interval

Table 4 Power of continuous variables affecting healing after TIP repair of hypospadias

Variables	AUC	Criterion	Sensitivity	Specificity	+ PV	-PV	*p* value
Age in years	0.696	≤ 2	37.8 (27.3–49.2)	100 (81.5–100)	100	26.1	0.0003 *
AGD in cm	0.798	> 5	54.88 (43.5–65.9)	88.89 (65.3–98.6)	95.7	30.2	< 0.001*
GMS score	0.900	≤ 7	86.59 (77.3–93.1)	83.33 (58.6–96.4)	95.9	57.7	< 0.001*
Plate width in mm	0.833	≥ 9	54.88 (43.5–65.9)	100.0 (81.5–100.0)	100.0	32.7	< 0.001*
SPL in cm	0.694	> 3.5	60.98 (49.6–71.6)	66.67 (41.0–86.7)	89.3	27.3	0.006*

PV predictive value, *AUC* area under the curve, *TIP* tubularized incised plate, *AGD* anogenital distance, *GMS* glans meatus shaft, *SPL* stretched penile length, *Cm* centimeter, *mm* millimeter

*Statistically significant AUC (*p* value < 0.05, null hypothesis AUC = 0.50)

76%, respectively, less likelihood for complications after surgery (Table 3).

The power of age, AGD, GMS score, plate width, and the SPL in predicting the healing as a main outcome for the TIP repair of hypospadias is shown in Table 4. These continuous variables had significantly larger AUC than the reference of 0.50. A patient's age ≤ two years had 100% specificity and 37.8% sensitivity for healing ($p<0.001$). An AGD > 5 cm had 54.9% sensitivity and 88.9% specificity ($p<0.001$). A GMS score ≤ 7 had 86.6% sensitivity and 83.3% specificity ($p<0.001$). A plate width ≥ 9 mm had 54.9% sensitivity and 100% specificity for healing ($p<0.001$). Lastly, an SPL > 3.5 cm had 61% sensitivity and 66.7% specificity for healing ($p<0.01$). Accordingly, the GMS criterion was both sensitive and specific for the healing outcome, while the plate width, AGD criteria and child's age were more specific than sensitive for healing following TIP repair of hypospadias (Table 4, Fig. 1).

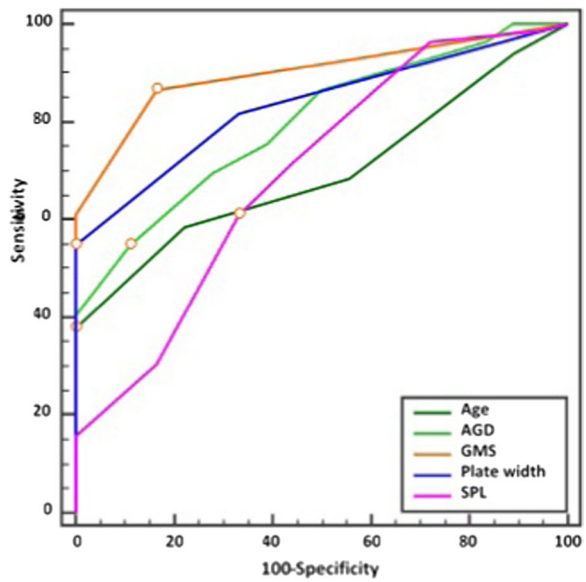

Fig. 1 ROC curves for continuous variables affecting healing after TIP repair of hypospadias. *ROC* receiving operating characteristic, *TIP* tubularized incised plate, *AGD* anogenital distance, *GMS* glans meatus shaft, *SPL* stretched penile length

4 Discussion

The TIP procedure gained popular acceptance worldwide as surgery for distal hypospadias repair. Two distinct reviews on hypospadias surgical repair done in North

America and in Europe, respectively, found that TIP urethroplasty was the supported strategy [8, 9]. Snodgrass initially portrayed it in 1994; the strategy is described primarily by doing urethral plate incision then tubularizing the plate to a neourethra. Along these lines, this strategy, thoughtfully direct with multiple modifications, has increased across the board acknowledgment as a solitary step procedure with low entanglement rates, demonstrated palatable results and great satisfactory outcomes [10].

AGD is almost twice as long in human males compared with females was identified by The US Environmental Protection Agency as a sensitive reproductive endpoint of masculinization. AGD is strongly related to serum testosterone in both men and women, meaning that longer AGD is associated with higher serum testosterone levels. In addition, shorter AGD is associated with severe anatomical forms of hypospadias and complex outcome of repair, and this could be explained by the complex techniques of repair and deficient healing promoter factors in such cases including EGF and microvascular density CD34 [11].

In our results, AGD > 5 cm was associated with successful outcome of TIP repair with 55% sensitivity and 89% specificity. In addition, the one-unit increase in AGD (95% CI 0.148–0.996, $p < 0.05$) was associated with 62% less likelihood for complications after surgery. This was comparable to other studies which stated that short AGD is related to severe hypospadias and thus more complex and difficult repair with increased risk of complications post-repair [12–14].

SPL is an important determinant for cosmetic and functional results after hypospadias surgery. Long-term patient satisfaction following hypospadias repair depends on penile size as an important reason for satisfied penile appearance and considered an indicator of prenatal androgen exposure [15]. In our results, SPL > 3.5 cm was associated with successful outcome of TIP repair with 61% sensitivity and 66% specificity. SPL in complicated versus uncomplicated cases was (3.3 ± 0.8 vs. 3.9 ± 0.9 cm), ($p < 0.01$).

In the current study, the complications rate was 18%. UCF and meatal stenosis were 14%. (Ten cases were diagnosed by inspection and meatal calibration at 1-month follow-up visit, while four cases were diagnosed at 6 months visit). Repair breakdown was 1%. (One case was diagnosed at 1-week follow-up visit by inspection.) Urethral stricture was 3%. (Three cases were diagnosed at 1-year follow-up visit by urethrogram under anesthesia.) In comparison to other investigations, the TIP repair when it is confined to primary distal hypospadias, the meatal stenosis and UCF rate, urethral stricture, and reoperation was 9.3%, 1.3%, and 4.5%, respectively [16].

Wilkinson et al. [17] detailed a nearly similar UCF and meatal stenosis rates, and snodgrass revealed a 2% fistula rate for the distal repairs [18]. In a meta-review of 53 distributed reports about TIP cases [19], the mean meatal stenosis rate was 2.1%, ranging from 0 to 17%, and the mean fistula rate was 5.9%, with a range from 0 to 16%. In another study [20], the mean meatal stenosis rate was 3.6%, extending from 0 to 6%, the mean fistula rate occurred in 6.7%, ranging from 0 to 9%, and the glandular dehiscence rate represented 1%, ranging from 0 to 8%.

The likelihood of complications was increased by 4 times with every year increase in patient's age (95% CI 1.554–10.357, $p < 0.01$). A patient's age ≤ two years had 100% specificity and 37.8% sensitivity for healing ($p < 0.001$). Perlmutter et al. (2006) stated comparable results; increasing age of child above 2 years was associated with increased risk of complications [21]. The best age for hypospadias repair was between 6 months up and 18 months according to the European guidelines. In contrast to our results, mean ± SD of age was 3.5 ± 1.5 years. Parents' cultural believes, socioeconomic and educational level could explain this [22].

Many surgeons choose hypospadias patients for TIP procedure on criteria such as small glans, shallow or flat urethral groove, long spongiosum defect, and redo repairs [23–25]. Opposite to our study, a large retrospective investigation of over 400 patients underwent by a single surgeon has detailed that no specific configuration inclines to stricture or fistula after TIP [26].

In our results, the one-unit increase in plate width (95% CI 0.068–0.869, $p < 0.05$) was associated with 76% less likelihood for complications after surgery. A plate width ≥ 9 mm had 54.9% sensitivity and 100% specificity for healing ($p < 0.001$). In contrasting youngsters and urethral plates with a width of < 8 mm versus wider ones, no critical distinction in results was inclined to complications [27]. In another study, depth of urethral groove did not significantly affect the urinary stream direction or the fistula rate, in spite that a neourethral caliber less than 8 mm after TIP was significantly related to increased stenosis rate [28].

Patients with distal penile meatal location were 8.2 times more likely to develop complications after surgical repair, compared to coronal or subcoronal meatal site (95% CI 1.020–66.520, $p < 0.05$). Patients with chordee degree < 30° were 11.6 times more likely for developing complications after surgical repair compared to absent chordee (95% CI 1.468–91.757, $p < 0.05$). In agreement to our study, other reports highlighted that ventral penile curvature was also accompanied by increased complication rates [29]. Penile curvature, especially moderate and severe chordee, meatal location, development of

spongiosum, and narrow width of urethral plate implemented a statistically significant higher complication rate [30].

In our study, we excluded chordee degree ≥ 30° because according to Snodgrass et al., a penile curvature ≥ 30 degree is considered a proximal hypospadias. Moreover, the long-term results of TIP in such categories of patients have more than 55% complications rate [26].

Arlen et al. [7] demonstrated that there was a strong correlation between complication risk and total GMS score. These findings were comparable to our findings in which GMS score in complicated versus uncomplicated cases was (8.3 ± 0.8 vs. 5.9 ± 1.6), ($p < 0.001$) and GMS score ≤ 7 had 86.6% sensitivity and 83.3% specificity. (The GMS criterion was both sensitive and specific for the healing outcome.) In Arlen study, there were contrary results at ours about significance of age, and location of urethral meatus. This difference could be identified because 38.6% of their patients treated with other procedures rather than TIP repair.

Patient's weight did not have a statistically significant correlation with the outcome of repair. There are significant correlations between AGD and body weight and between AGD and the cube root of body weight [31]. Weight was measured in both complicated and uncomplicated groups that is homogenously distributed between both groups to avoid bias in measuring AGD in both groups that can affect the tested relation.

Torsion degree did not have a statistically significant relation with the outcome of repair. Our results agreed with these results obtained by Bhat et al. [30] in which penile torsion did not have any relation with complications after TIP repair.

The limitations of our study were relatively small sample size and short period of postoperative follow up 1 year only.

From our point of view based on our results, we could conclude the proper suggested criteria for successful outcome of TIP distal hypospadias repair were as follows: absent chordee, coronal/subcoronal meatal location, plate width ≥ 9 mm, AGD > 5 cm, age of patient ≤ 2 years old, GMS score ≤ 7, SPL > 3.5 cm and grooved glanular shape.

5 Conclusions

The proposed successful criteria of TIP Repair were absent chordee, coronal/subcoronal penile meatal location, plate width ≥ 9 mm, AGD > 5 cm, age of patient ≤ 2 years old, GMS score ≤ 7, SPL > 3.5 cm and grooved glanular shape.

Abbreviations

TIP: Tubularized incised plate; AGD: Anogenital distance; SPL: Stretched penile length; GMS: Glans meatus shaft; SD: Standard deviation; UCF: Urethrocutaneous fistula; HCG: Human chorionic gonadotropin; SPSS: Statistical package for the social sciences; OR: Odds ratio; ROC: Receiving operating characteristic; AUC: Area under curve; EGF: Epidermal growth factor; Cm: Centimeter; mm: Millimeters; kg: Killogram.

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Authors' contributions

All authors were involved with each of the below activities, KM and HA were shared in conception and design of the study. KM and EA and AK were shared in generation, collection, assembly, analysis and interpretation of data. KM and MS were shared in drafting and revision of the manuscript. All authors were shared in approval of the final version of the manuscript.

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Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

All patient's caregivers signed informed consent according to the principles embodied in the Declaration of Helsinki (https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/) for all investigations involving human materials and approved by Suez Canal University ethical committee under number 4071/2020.

Consent for publication

Not applicable in this section.

Competing interests

The authors declare that they have no competing interests.

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