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Comparison between Tran abdominal and trans anal one stage pull through in Hirschsprung disease

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ABSTRACT

Background: Hirschsprung's disease (HD) is one of the commonly studied diseases among pediatric surgeons and researchers. It is also known as intestinal aganglionosis, which is a kind of birth defects mainly expressed as partial or complete absence of ganglion cells of the intestinal tract.

Objective: The aim of the current work was to evaluate the management of children with Hirschsprung's disease by one stage pull-through Soave procedures (transanal and trans-abdominal one stage pull-through) concerning perioperative, short term outcomes and complications.

Patients and methods: This randomized controlled trial study included a total of 32 patients subjected to transanal and transabdominal one stage pull-through procedures for management of Hirschsprung's disease. Patients were recruited from the Inpatient Clinic, Pediatrics Surgical Department, Assiut University Hospitals. This study was conducted between April 2015 to March 2019 and followed up at our clinics.

Results: Comparison of the rates of late post-operative complications among the studied groups revealed that regarding post-operative incontinence, group A had statistically insignificant (p = 0.723) lower rates (50%) compared with group B (56%). Likewise, rates of adhesive intestinal obstruction were insignificantly (p = 0.310) higher (6.2%) in comparison with group B (0%). There was statistically significant (p = 0.001) longer duration of hospital stay among patients in group A (11.1 ± 6.4days) compared with patients in group B (5.0 ± 1.4 days).

Conclusion: It could be concluded that the advantages of TERPT include a good cosmetic effect, short hospital stays, safe, and less surgical site infection compared to transabdominal procedures.

Keywords: Hirschsprung Disease, One stage pull-through transanal and trans-abdominal.

INTRODUCTION

Hirschsprung's disease is one of the commonly analyzed diseases among researchers in pediatric surgery. This condition was first described by Harald Hirschsprung as a congenital megacolon in 1888. Since then, various methods for diagnosis and treatment of Hirschsprung's disease have been introduced [1, 2].

The disease incidence is about 1 per 5000 live births, males are more likely to be affected than females. Although Hirschsprung disease usually occurs in infancy, some people will present with persistent, severe constipation in the later life [3]. The basic principle for the definitive surgical therapy is resection of the aganglionic bowel followed by anastomosis [4].

The surgical management of Hirschsprung's disease (HD) is rapidly changing from the multi-staged procedure to a single-stage one. This evolution aims at reducing the cost, hospital stay, and the morbidity associated with the staged procedures [5].

Swenson and Bill [6] performed the first successful corrective surgery. The procedure, soon became popular as Swenson's procedure, brought a realistic hope that children with HD can be cured [7].

Duhamel [8] described another technique different from Swenson. The principle of the procedure is partially bypassing the rectum and performance of end to side anastomosis. **Soave** [9] described the details of endorectal approach for pull through. The endorectal pull-through was originally described through transabdominal approach.

In 1998, De la Torre-Mondragon proposed a new treatment called single-stage TERPT, which is more suitable for infants. This minimally invasive surgery with an anal approach has become an increasingly popular method for the treatment of HD, eliminating the risk of complications such as abdominal adhesions and pelvic nerve injury [10].

The advantages of TERPT include a good cosmetic effect and a short hospitalization time, and its safety has been proved by many studies [11, 12, 13]. However, there are a variety of ways to choose surgery in clinical practice, and no consensus has been reached.

The current study was aimed to evaluate the management of children with Hirschsprung's disease by one stage pull-through Soave procedures (transanal and trans-abdominal one stage pull-through) concerning perioperative, short term outcomes and complications.

PATIENTS AND METHODS

This randomized controlled trial study included a total of 32 patients subjected to transanal and transabdominal one stage pull-through procedures for

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management of Hirschsprung's disease. Patients were recruited from the Inpatient Clinic, Pediatrics Surgical Department, Assiut University Hospitals. This study was conducted between April 2015 to March 2019 and followed up at our clinics.

Sample Size Calculation: Sample size calculation was carried out using G*Power 3 software **[14].** A calculated minimum sample of 32 patients was needed, based on a two-group 1:1 design, would have 80% power to detect an effect size of 0.5 in the rate of postoperative complications, at a one-sided significance level of 0.05.

Inclusion criteria: All patients aged 3 months to 16 years, from both sexes, have no operation before (Denovo), associated with no other complex congenital malformations were included for the current study.

Exclusion criteria: patients with recurrence and with associated other complex congenital malformations that necessitates other combined operation.

All patients were subjected to:

History taking including time of pass meconium post delivery, general examination including weight, height, temperature, manifestations of any systemic diseases or congenital anomalies.

- Local examination of the abdomen for distension, scars, tenderness, and palpable masses.
- Perianal region examination for perianal fistula, position of the anus, anal wink, anal scars, and fissures.

Recruitment and randomization:

After completion of the baseline assessment, participants were randomly allocated to one of the two intervention groups: **Group A:** 16 patients underwent trans-abdominal one stage pull-through procedures and **Group B:** 16 patients underwent transanal one stage pull-through procedures). Allocation was done by the biometrician based on a predetermined list generated with a blocked randomization SPSS procedure with a fixed block size. To prevent possible bias, study personnel involved in the recruitment and the baseline assessment did not have access to the randomization lists and were not aware of the block size. Conversely, the biometrician does not have influence on the recruitment procedure. Descriptive data about patients baseline sociodemographic and clinical characteristics were recorded.

Postoperative follow up: parenteral antibiotic was given for 3 days post-operative.

- IV fluid were stopped once intestinal movement being normal: with oral feeding step by step then discharge.
- Follow up and record early postoperative complications.
- Patient followed up at the outpatient clinic 2 weeks, at the end of first month, 3-month and after 6 months postoperatively.

Ethical considerations:

Approval for this study was obtained from Institutional review board (IRB) of Faculty of Medicine, Assiut University Hospital prior to study execution. In addition, all participants/caregivers received a written consent form. The informed consent was clear and indicated the purpose of the study, and they were free to participate or withdraw at any time without any obligation. Furthermore, participants' confidentiality and anonymity were assured by assigning each participant with a code number for the purpose of analysis only. The study was not based on any incentives or rewards for the participants and was abided to the guidelines of Helsinki Declaration and the CONSORT guidelines.

Statistical analysis

Data were verified, coded by the researcher, and analyzed using IBM-SPSS version 24. Descriptive statistics: Means, standard deviations, medians, ranges, and percentages were calculated. Test of significances: chi-square/Fisher's Exact test was used to compare the difference in distribution of frequencies among different groups. For continuous variables, independent t-test/Mann Whitney U test analysis was carried out to compare the means and medians for parametric/non-parametric data. A p-value < 0.05 was considered significant.

RESULTS

Of the 16 patients in the trans-abdominal group, 11 (69%) were males and 5 (31%) were females. The patients' age ranged between 1.5 and 15.5 years with a mean of 5.5 ± 3.3 years. Also, the mean patient's age at operation was 3.3 ± 3.3 years, with a median of 2.5 (0.5 – 15 years). Regarding transanal group, about four-fifth (n=13) of the sample was males and one-fifth (n=3) was females. The patients' age ranged between 1 and 12.5 years with a mean of 3.2 ± 2.6 years. Also, the mean patient's age at operation was 2.2 ± 2.1 years, with a median of 1.5 (0.3 – 1.8 years)**.**

Patients group A were older than those in group B, and this was statistically insignificant ($p > 0.002$)**.** As well, patients in in group A were older at time of operation than those in group B, and this was statistically insignificant ($p > 0.043$). Regarding sex, there was statistically insignificant relationship ($p = 0.343$) **(Table 1).**

Table (1): Baseline sociodemographic characteristics of the studied groups.

	Trans-abdominal (n=16)	Transanal (n=16)	P-value
Age/years			

• **Mean ± SD**	5.50 ± 3.3	3.19 ± 2.2	**= 0.002***
• **Median (Range)**	5 (1.5 – 15.5)	2.5 (1 – 12.5)	
Sex			
• **Female**	5 (31.2%)	3 (18.8%)	= 0.343**
• **Male**	11 (68.8%)	13 (81.2%)	
Age at Operation/years			
• **Mean ± SD**	3.27 ± 3.1	2.21 ± 2.1	**= 0.043***
• **Median (Range)**	2.5 (0.5 – 15)	1.5 (0.3 – 11.8)	

*Mann-Whitney U test was used to compare the median differences.
**Fisher's Exact test was used to compare the percentages between groups.
P value 0.005 significant

The operative data comparisons between the two studied groups. The average operative time was higher (ranged between 120and 180 minutes with mean of 138 ± 24 minutes) in the transabdominal group than transanal group (ranged between 60 and 90 minutes with mean of 72 ± 12 minutes) (Table 2).

Table (2): Mean operative time comparison of the studied groups.

	Trans-abdominal (n=16)	Transanal (n=16)	P-value
Operative Time/hour			
• **Mean ± SD**	138 ± 24	72 ± 12	**= 0.002***
• **Median (Range)**	2.3 (2 – 3)	1.2 (1 – 1.5)	

*Independent t-test was used to compare the mean differences
**Fisher's exact test was used to compare the percentages between groups

Rate of wound sepsis was higher in group A representing about 19% (n=3) compared with group B (0%) and this was statistically significant (p = 0.034). On the other hand, there was non-significant association between type of operation and rate of enterocolitis (p = 0.699) i.e., rate was 31% in group A vs. 25% in group B.

Moreover, only one case (6.3%) of group A underwent rectal retraction managed by follow up and all cases of group B did not had retraction, and this was statistically insignificant (p = 0.500). Regarding post-operative vomiting and distension, group A had statistically significant (p = 0.003) higher rates (62.5%) compared with group B (12.5%). Likewise, rates of constipation were significantly (p = 0.039) higher (44%) in comparison with group B (19%).

Contrarily, post-operative bleeding was reported in only one case (6.3%) of group B and this was managed by follow up and blood transfusion, while all cases of group A had no bleeding, and this was statistically insignificant (p = 0.500).

Likewise, partial disruption of the anastomosis was reported in only one case (6.3%) of group A.

On the other hand, patients in group A had higher rates of post-operative paralytic ileus (37.5%) than group B (0%), and this was statistically significant (p = 0.018). Similarly, three patients (18.8%) in group A reported significant pain that was treated with strong analgesics, whereas pain was tolerable in group B (0%) and this was statistically significant (p = 0.034) (Table 3).

Table (3): Early post-operative complication data comparison of the studied groups.

	Trans-abdominal(n=16)	Transanal (n=16)	P-value*
Wound Sepsis			

• **No**	13 (81.2%)	16 (100%)	**= 0.034**
• **Yes**	3 (18.8%)	0 (0%)	
Enterocolitis			
• **No**	11 (68.8%)	13 (75%)	= 0.699
• **Yes**	5 (31.2%)	3 (25%)	
Retraction of the Rectum			
• **No**	15 (93.7%)	16 (100%)	= 0.500**
• **Yes**	1 (6.3%)	0 (0%)	
Vomiting and Distention			
• **No**	6 (37.5%)	14 (87.5%)	**= 0.003**
• **Yes**	10 (62.5%)	2 (12.5%)	
Constipation			
• **No**	9 (56.2%)	13 (81.2%)	**= 0.039**
• **Yes**	7 (43.8%)	3 (18.8%)	
Bleeding			
• **No**	16 (100%)	15 (93.7%)	= 0.500
• **Yes**	0 (0%)	1 (6.3%)	
Partial disruption of the anastomosis			
• **No**	15 (93.7%)	16 (100%)	= 0.500
• **Yes**	1 (6.3%)	0 (0%)	
Paralytic Ileus			
• **No**	10 (62.5%)	16 (100%)	**= 0.018**
• **Yes**	6 (37.5%)	0 (0%)	
Pain need potent analgesia			
• **No**	13 (81.2%)	16 (100%)	**= 0.034**
• **Yes**	3 (18.8%)	0 (0%)	

****Fisher's Exact test was used to compare the percentages between groups**

Comparison of the rates of late post-operative complications among the studied groups revealed that regarding post-operative incontinence, group A had statistically insignificant (p = 0.723) lower rates (50%) compared with group B (56%). Likewise, rates of adhesive intestinal obstruction were insignificantly (p = 0.310) higher (6.2%) in comparison with group B (0%). Also, patients in group A had higher rates of post-operative stenosis (25%) than group B (12.5%), and this was statistically insignificant (p = 0.654)**.** Among those underwent dilatation by Hegar dilator size10-18 all of them improved, only one case (6.7%) failed (in group A (trans-abdominal)) and managed by strictureplasty.

There was statistically significant (p = 0.001) longer duration of hospital stay among patients in group A (11.1 ± 6.4days) compared with patients in group B (5.0 ± 1.4 days) **(Table 4)**.

Table (4): Late post-operative complication data comparison and hospital stay of the studied groups.

	Trans-abdominal (n=16)	Transanal (n=16)	P-value*
Incontinence			
• **No**	8 (50%)	7 (43.8%)	= 0.723

• **Yes**	8 (50%)	9 (56.2%)	
PO Adhesive Intestinal Obstruction			
• **No**	15 (93.8%)	16 (100%)	= 0.310
• **Yes**	1 (6.2%)	0 (0%)	
Stenosis			
• **No**	12 (75%)	14 (87.5%)	= 0.654
• **Yes**	4 (25%)	2 (12.5%)	
Length of Hospital Stay/days			
Mean ± SD	11.06 ± 6.4	5.00 ± 1.4	**= 0.001***
Median (Range)	10.5 (1 – 20)	4.5 (3 – 7)	

**Fisher's Exact test was used to compare the percentages between groups

DISCUSSION

We included a total of 32 cases diagnosed with Hirschsprung disease who were randomly allocated into two groups; Group A included 16 cases who underwent the transabdominal approach, and Group B included the remaining 16 cases who underwent the transanal route. The included cases had mean ages of 3.27 and 2.21 at the operation time. Despite the small difference, age was significantly younger in Group B (p = 0.043).

Tannuri *et al.* [15] reported that the mean age of the included cases was significantly older in the abdominal group (p = 0.001). It had a mean value of 42 months compared to 11 months in the transanal group.

In another study handling the same comparison, **Kim *et al.*** [16] reported an older age, the included cases had mean ages of 13.5 and 5.8 years in the transabdominal and transanal groups respectively, with a significant difference between the two groups (p = 0.003).

This difference could be explained by differences in the medical setup of each country, and delayed referral from the surrounding rural areas.

In the current study, the gender of the included cases was not significantly different between the two groups (p = 0.343). Males represented 68.8 and 81.2% of cases in Groups A and B respectively, while the remaining cases were females.

In agreement with or findings, another study **Romero *et al.*** [17] reported that males represented 79.3 and 87.5% of cases in the transabdominal and transanal groups respectively, with no significant difference between the two groups (p = 0.48).

Furthermore, **Kim *et al.*** [16] reported that male patients represented 82 and 83% of the included cases in the same groups respectively, with no significant difference between the two groups (p = 0.871). **Hadidi** [18] also reported that operative time had mean operative time of 150 and 90 minutes in the transabdominal and transanal groups respectively.

Regarding operative time in our study, it was significantly shorter in the transanal group (p = 0.002). It had mean values of 138 and 70 minutes in Groups and B respectively.

Romero *et al.* [17] confirmed the previous findings regarding the decreased operative time with the transanal approach. It had a mean value of 133.2 minutes compared to 204 minutes in the transabdominal approach (p < 0.001).

In our study, surgical site infection was encountered in 18.8% of cases in the transabdominal group, compared to no cases in the other group. It was evident that this complication was significantly associated with the transabdominal approach (p = 0.034).

Likewise, **Tannuri *et al.*** [15] reported that surgical site infection was noted in 13.8% of the transabdominal cases versus no cases in the transanal group, with a significant difference between the two groups (p = 0.03).

In the current study, enterocolitis occurred in 31.2 and 25% of cases in Groups A and B respectively, with no significant difference between the two groups (p = 0.699).

No significant differences in post-pull-through enterocolitis between endorectal and transabdominal procedures have been published in comparable studies [19, 20].

Another study **Stensrud *et al.*** [21] reported no significant difference between the transabdominal and transanal approaches regarding that complication, which was encountered in 25 and 4% of cases in the two groups respectively. Statistical analysis showed absence of any statistical significance despite that difference (p = 0.056).

On the other hand, **Hadidi**[18] reported slightly higher incidence of the same complication in the transabdominal group (12%) compared to the transanal one (4.4%). The difference in the incidence of enterocolitis may be related to the length of aganglionic muscle cuff left behind and whether posterior midline myotomy was carried out.

In our study, post-operative vomiting and distension were encountered in 62.5 and 12.5% of cases in Groups A and b respectively, with a significant increase in its incidence in the transabdominal group (p = 0.033). That would be reasonable with the increased incidence of post-operative paralytic ileus in the transabdominal group compared to other one.

Contrarily, **Kim *et al.*** [16] reported that the same complication was noted in 6 and 4% of cases in the transabdominal and transanal groups respectively.

In the current study, post-operative constipation was significantly more encountered in the transabdominal group (p = 0.039). It was reported by 43.8% of cases in that group compared to 18.18% of cases in the transanal cases.

Of course, the previous findings reflect a considerable but not significantly better outcome in favor of the transanal group. Comparable reports achieved similar results [20, 21, 22].

On the other hand, another study **Romero *et al.*** [17] reported no significant difference between the two approaches regarding post-operative constipation (p = 0.09). Nonetheless, the incidence was still higher in the transabdominal approach (27.6%) compared to the trans anal one (8.3%). Also, **Stensrud *et al.*** [21] reported that constipation was reported by 25 and 17% of cases in the transanal and transabdominal groups respectively, with no significant difference between the two groups.

The incidence of post-operative bleeding did not show any significant difference between our two study groups (p = 0.5). It occurred in 0 and 6.3% of cases in the groups A and B respectively.

However, **Onishi *et al.*** [23] reported that the transanal approach was associated with a. significant decrease in blood loss compared to the transabdominal approach. Another study **Elrouby *et al.*** [24] confirmed the previous findings.

In our study, post-operative incontinence was not significantly differ between the two groups (p = 0.723). It was reported by 50 and 56.2% of cases in groups A and B respectively.

Likewise, **Romero *et al.*** [17] confirmed the previous findings as no significant difference was noted regarding the incidence of incontinence neither in children younger nor older than 5 years (p = 0.15 and 0.17 respectively. **Tannuri *et al.*** [15] reported that incontinence was reported by 6.9 and 8.3% of cases in the transabdominal and transanal groups respectively, with no significant difference between the two groups (p = 1).

On the contrary, **El-Sawaf *et al.*** [19] noted a significantly (two- fold) better continence score in the abdominal group than in the transanal group by examining subcategories of the questionnaire. The proper explanation for the previous findings is that the transanal approach requires traction on the anal sphincters for endorectal dissection and anastomosis. Such manipulation of the anal canal may induce overstretching of the anal sphincter muscle and has been suggested as a potential cause of fecal incontinence [19, 25].

During the follow up period scheduled in the present study, adhesive intestinal obstruction was encountered in only one case in the transabdominal group (6.2%), with no difference between the two groups (p = 0.310). In line with our findings, intestinal obstruction was encountered in 1% of cases in the two groups, with no significant difference between them regarding the same parameter (p > 0.05) [16].

In the current study, stenosis was encountered in 25 and 12.5% of cases in Groups A and B respectively, with no significant difference between the two groups (p = 0.654). All cases were well-managed by frequent dilatation, while only one case required stricturoplasty in the transabdominal group.

In a large series, the stricture rates after pull-through procedures range from 4% to 19% [12, 16, 27]. **Obermayr *et al.*** [27] described a 12% incidence of symptomatic anastomotic stricture after TERPT. The previous reports agree with our findings.

In our study, the duration of hospitalization was significantly prolonged in the transabdominal group compared to the transanal one (11.06 vs. 5 days respectively – p = 0.001). of course, the increased complication rates in the transabdominal group will have its impact on the prolongation of the hospital stay.

Likewise, **Romero *et al.*** [17] conducted in 2011 reported that the duration of hospitalization showed a significant increase with the transabdominal approach. Hospital stay had mean values of 9.8 and 17.7 days in the transanal and transabdominal groups respectively.

The previous findings were also confirmed by **Hadidi** [18] study which reported that the duration of operation had median durations of 7 and 3 days in the transabdominal and transanal approaches respectively. **Tannuri *et al.*** [15] also confirmed the previous findings.

CONCLUSION

Our study results support use of TERP as an excellent surgical approach for children with Hirschsprung's disease. It could be concluded that the advantages of TERPT include a good cosmetic effect, short hospital stays, safty, and less surgical site infection compared to transabdominal procedures.

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