

Research Journal of Pharmaceutical, Biological and Chemical Sciences

Comparing the New and Old Pull through Surgery Techniques; a Randomized Control Trial.

Seyed Mohammad Vahid Hosseini¹, Manoochehr Kamali², Hamid Reza Farahmand^{3*}, and Shahram Zare⁴, Seyed Vahid Hosseini⁵

¹Department of Pediatric surgery, Clinical Research Development Centre of Children Hospital, Hormozgan University of Medical Sciences, Bandar Abbas, Iran

²Anesthesiology, Critical Care and Pain Management Research Center, Hormozgan University of Medical Sciences, Bandar Abbas, Iran.

³Department of Surgery, Shahid Mohammadi Hospital, Hormozgan University of Medical Sciences, Bandar Abbas, Iran.

⁴Department of Social Medicine, School of Medicine, Hormozgan University of Medical Sciences, Bandar Abbas, Iran.

⁵Division of Colorectal Surgery, Department of Surgery, Shiraz University of Medical Sciences

ABSTRACT

Hirschsprung disease (HD) is the most prevalent surgical disease among children. It occurs due to lack of ganglia cells in the distal colon. The most common treatment is surgery which is performed using pull through technique. The aim of this study was to compare the new and old pull through surgery techniques. This randomized control trial was conducted in 2014 in southern Iran. HD was diagnosed by history, clinical examination, barium enema and manometry findings. Continuous sampling was used to select the participants. The age and condition severity of patients of both groups were matched. The cuff muscle will not be damaged in the new method and duration of hospitalization, intra-operative bleeding, and surgery duration of both groups will be collected. All patients were followed up for one year to evaluate constipation, encopresis, surgical site infection, hypertrophic scar, fecal leakage, and early or late enterocolitis. The difference between anesthesia time, number of patients who needed transfusion, or number of those who encountered constipation, early or late enterocolitis was significant. The anesthesia time, transfusion requirement, and the frequency of late enterocolitis was lower in the new method. The frequency of constipation and early enterocolitis was higher in the new method. The difference between other factors was not significant. The new trans-anal pull through method is more efficient and has better results and needs more attention and evaluation.

Keywords: Hirschsprung's Disease, Surgery, Pull Through

**Corresponding author*

INTRODUCTION

HD is a developmental disorder that occurs due to absence of ganglia cells in the distal colon. This aganglionosis leads to an intestinal nervous system dysfunction [1]. HD is the main congenital reason for functional obstruction [2] and is diagnosed in the first days after birth [3]. Studies in northern England have shown that the prevalence of HD is 1.26 per 10.000 and occurs among the male population twice as females [4]. Some studies show a prevalence of 1.09 per 10.000 people in Europe and an increased prevalence over time have been suggested [5].

Imaging methods are helpful. Anorectal manometry, pathologic findings are also useful tools for HD diagnosis [6]. The only treatment for HD is surgery. Untreated HD can lead to death due malnutrition, sepsis and intestinal perforation. Even though surgery is the common treatment, it may cause chronic complications such as constipation, encorpresis, and enterocolitis[7].

Diverting colostomy is the traditional treatment and the definite treatment is postponed until the patient achieves ten kilograms [8]. During the last decade the treatment trend has changed and a life without colostomy is demanded. De la Torre Modragon et al have developed trans-anal endorectal pull through (TAEPT). This method has been the most advanced minimally-invasive treatment for HD and its results were better than the two or three step methods [9]. Laparotomy is not needed in this method, minimum rectum manipulation occurs, the cuff muscles are retained and less damage is caused to the sphincters [10].

Due to the importance of HD, the aim of this study was to compare the new TAEPT method with the old technique.

METHOD

This was a randomized clinical trial that was conducted in 2014 in southern Iran. The aim of this study was to compare the new and old surgery technique. Our target population is all patients diagnosed with HD. The samples of this study were selected from one to four year old children suffering from HD. Patients were diagnosed using history, clinical examination, barium enema and manometry findings. Continuous sampling was used to select the participants. Patients were matched according to age and severity of clinical symptoms and were allocated into two groups. In the old method, patients were placed into prone position. After operation prep, around the anal region was cut with a scalpel and anus, its mucosal tissue and cuff muscle were cut and removed. In the new method, the aganglionic region underwent trans-anal mucosectomy with frozen section and myomectomy was performed in four quadrants. Unlike the old method, the cuff muscle was not damaged. Thus, the risk of interventional damages to the intestine and discharge leakage was minimized. Also, a rectal tube was placed in the anus to prevent early obstruction. According to manometry findings, normal rectal tone is when the rectal stretch increases and the internal sphincter relaxes using 0.5 cc rectal balloon. It is not considered as normal rectal tone if the internal sphincter does not relax. According to manometry findings, patients are divided into four groups:

- Patients who need 5 – 10 cc balloon to maintain normal tone.
- Patients who require a dilated balloon (volume above 10 cc) (dilated).
- Patients with hyperactive external muscles that relax after a while (retentive)
- Patients who will not experience an increased tone and normal reflex in the internal sphincter with a 10 cc balloon.

Patients with a dilated reflex were treated with medication and enema. Retentive patients who had increased inter-muscular tone were treated with botulism toxin and medication. In case of unsuccessful treatment patients went through rectal biopsy and pull through surgery. The duration of hospitalization, amount of intra-operative blood loss, and surgery duration of both groups were collected. All participants were followed up two weeks after surgery and at the end of each month (for one year) and were evaluated for constipation symptoms, encorpresis, surgical site infection, hypertrophic scar, fecal leakage, and early or late enterocolitis. Patients with central nervous system, motor impairment, myopathy, congenital perineal diseases, congenital heart disease, and patients who underwent laparotomy due to acute abdomen or were unavailable for follow up were excluded from the study. All the parents became aware of complications and benefits of the both methods and written consent was provided by the parents. Data were entered SPSS

software and analyzed using descriptive statistics such as mean, standard deviation, frequency, chi-square, independent sample t-test.

RESULTS

Among 60 participants, 22 were allocated into the old method group (A) and 38 into the new method group (B). The mean anesthesia time of group A patients was 97.5 ± 42.110 minutes and group B was 58.82 ± 16.168 minutes. According to the p-value which was below 0.05, it can be concluded that this difference was significant and thus, the mean anesthesia time was shorter in group B ($p < 0.001$). The duration of hospitalization of group A and group B was 4.23 ± 1.232 days and 4.24 ± 0.768 days, respectively. This difference was not statistically significant ($p\text{-value} = 0.640$). However, the mean duration of hospitalization of group AB was longer than group A. Seven patients (31.8%) of group A needed blood transfer while only two patients (5.3%) of group B required that. This difference was significant ($P\text{-value} = 0.0167$). This showed that patients of group A required more blood transfusion. The frequency and prevalence of surgical site infection of group A and group B patients was 4 (18.2%) and 10 (26.3%), respectively. This difference was not statistically significant ($P\text{-value} = 0.6905$). Encopresis was present in four patients (18.2%) of group A and five patients (13.2%) of group B. According to the $p\text{-value} = 0.8828$, this difference was not significant. The incidence of constipation among patients of group A and group B was five (22.7%) and 21 (55.3%), respectively. Since this difference was significant ($p\text{-value} = 0.0289$). This shows that the incidence of constipation was higher among group B patients. Fecal leakage was seen in nine patients (40.9%) of group A and nine patients (23.7%) of group B. There was no significant difference seen ($P\text{-value} = 0.2676$). No patients of group A experienced early enterocolitis while 16 patients (42.1%) of group B were diagnosed with it. This difference was statistically significant ($p\text{-value} = 0.0012$). Thus, patients who underwent the new method had a higher incidence of early enterocolitis. Late enterocolitis was seen in eight patients (36.4%) of group A and no patients of group B. According to the $P\text{-value} = 0.0003$, this difference was significant and patients of group A had a higher incidence of late enterocolitis. Four patients (18.2%) of group B and 16 patients (42.1%) of group A experienced anal stenosis. This difference was not statistically significant ($p\text{-value} = 0.1078$). Among patients of group A, seven patients (31.8%) experienced post-surgical hypertrophic scars while 14 patients (36.8%) of group B patients experienced post-surgical hypertrophic scars. The p-value of 0.9120 showed that this difference was not significant.

DISCUSSION

HD is one of the most common surgical diseases of childhood and its diagnosis and treatment is a challenge [11-13]. One of the most used surgical techniques which had better results is trans-anal pull through method [14]. The aim of this study was to compare the old and new techniques of pull through surgery.

The mean surgery duration of the new technique was 58.82 ± 16.168 minutes, which was significantly shorter than the old technique. The results of most studies assessed the old technique; Ali et al [15] conducted this study on one month old newborns and the duration was 90 ± 18 . Hadidi et al [16] showed a surgical duration of 90 minutes, Elhalaby et al [17] showed duration of 120.2 ± 27.8 minutes, Teeraratkul et al [18] showed duration of 110 to 180 minutes and Bhatia et al [19] showed a surgical duration of 60 minutes. The new surgical method can significantly decrease the duration of surgery.

The hospitalization duration of the new technique was 4.24 ± 0.768 days which was not statistically different than the old method. Other studies show different results. Dehghan et al [20] showed a 8.76 ± 0.66 days hospital stay, Bhatia et al [19] ten days, Teeraratkul et al [18] showed six to seven days and Aslanabadi et al [21] showed a hospitalization duration of 3.05 ± 0.86 days. Overall, it is estimated that this technique has no effect on duration of hospitalization.

The amount of blood transfusion for patients during surgery was significantly less in the new technique group compared to group A ($p\text{-value} = 0.0167$). In this study, 5.3% of patients of the new method group required blood transfusion while Elhalaby et al [17] showed that this amount was 25% and 13.9% in two different age groups. Ali et al [15] showed no requirement for blood transfusion and Rouzrokh et al [22] showed that only one patient required transfusion. More studies are needed to investigate this issue.

In our study, 26.3% of patients of group B experienced surgical site infection and this incidence was not statistically different than group A (p -value= 0.690). Dehghan et al [20] and Zhang et al [23] showed that no patients who were operated using the old technique experienced surgical site infections.

In our study, encopresis was seen in 13.2% of patients of group B. The incidence of encopresis was not different among both groups (p -value= 0.8828). Teitelbaum et al [24] showed that in two old methods of trans-anal the incidence was one and three percent, Kim et al [25] showed an incidence of ten percent, Hadadi et al [16] showed an incidence of 0%, Zhang et al [23] also showed an incidence of 0%, Romero et al [14] demonstrated a 18% incidence. Some conducted studies showed that balking the defects of the internal sphincter will improve fecal incontinence function [26].

Among all group B patients, 55.3% suffered from constipation and these patients were more at risk for constipation compared with other patients (p -value= 0.0289). The incidence of constipation was 0% in a study conducted by Giuliani et al [27], 8.3% in a study conducted by Romero et al [14], 10% in a study conducted by Gosemann et al [28], and 12% in a study conducted by Dehghan et al [20]. Stensrud et al [29] also conducted a study using two methods of trans-anal and the incidence of constipation was 25% and 17%. As it can be seen, the incidence of trans-anal is higher in the new method.

Many patients (42.1%) of the new method group experienced early enterocolitis and this incidence was higher than the control group (p -value= 0.0012). On the other hand, none of the patients of group B experienced late enterocolitis and this was significantly lower than the control group (p -value= 0.0003). The incidence of late enterocolitis was 4.41% in a study conducted by Hadadi et al [16], 8.3% in a study conducted by Romero et al [14], 9.16% in a study conducted by Dahal et al [30] and 5% in a study conducted by Rouzrokh et al [22]. Early or late enterocolitis was not mentioned.

In our study, 42.1% of patients of group B encountered anal stenosis. This incidence was not significantly higher than patients of group A (p =0.1078). Other studies have also demonstrated frequency of anal stenosis, for example, the shown incidence was 12% by Rouzrokh et al [22] study, one percent in Kim et al study [25], 4.2% by Romero et al [14], 8% by Dehghan et al [20]. Most studies have shown a higher incidence than our study. However, further studies are needed for a comprehensive conclusion.

Hypertrophic scar was seen in 36.8% of patients who underwent the new technique which was more than the patients of the other group. However, this difference was not significant (p =0.9120). The incidence of hypertrophic scar in the study conducted by Dehghan et al [20], Aslanabadi et al [21] and Ali et al [15] was 3.22%, 0% and 0%, respectively.

Articles that were mentioned earlier have addressed the old trans-anal pull through method. Thus, in order to fully discuss this study, articles that have addressed the new method should also be addressed. Hosseini et al [31] conducted a study to evaluate the new method and showed that 40% of patients who encountered early obstruction had recovered after two months. Also, six percent of their participants encountered anal stenosis which was lower than our study. They reported no cases of discharge or peritonitis.

CONCLUSION

Our study showed that the new method of trans-anal pull through can be more efficient on most variables and have better results compared to the old technique. However, more studies are required for evaluation.

Limitations

Lack of cooperation of some parents

Suggestions

This study ought to be conducted in different situations and other age groups in other parts of the world with a higher study sample, follow-up time and number of evaluated parameters.

ACKNOWLEDGEMENTS

This study was the result of a general surgical resident thesis. We would like to thank all patients, parents, professors and personnel of Koodakan Hospital of Bandar Abbas.

REFERNCES

- [1] Tam PK, Garcia-Barceló M. *Pediatr Surg Int* 2009;25(7):543-58.
- [2] Gershon MD, Ratcliffe EM, editors. *Developmental biology of the enteric nervous system: pathogenesis of Hirschsprung's disease and other congenital dysmotilities. Seminars in pediatric surgery*; 2004: WB Saunders.
- [3] Kenny SE, Tam PK, Garcia-Barcelo M, editors. *Hirschsprung's disease. Seminars in pediatric surgery*; 2010: Elsevier.
- [4] Best KE, Glinianaia SV, Bythell M, Rankin J. *Birth Defects Research Part A: Clinical and Molecular Teratology* 2012;94(6):477-80.
- [5] Best KE, Addor MC, Arriola L, Balku E, Barisic I, Bianchi F, et al. *Birth Defects Research Part A: Clinical and Molecular Teratology* 2014;100(9):695-702.
- [6] Szyłberg Ł, Marszałek A. *A Systematic Review Of Current Literature*. 2013.
- [7] Tjaden NEB, Trainor PA. *Transl Rese* 2013;162(1):1-15.
- [8] Muensterer OJ, Chong A, Hansen EN, Georgeson KE. *J Gastrointest Surg* 2010;14(12):1950-4.
- [9] Langer JC. *Hirschsprung disease. Fundamentals of pediatric surgery*: Springer; 2011. p. 475-84.
- [10] Thapar N. *J Pediatr GastroenterolNutr* 2009;48:S92-S4.
- [11] Hosseini S, Zarenezhad M, Sabet B, Maleki M. *Arch Int Surg* 2012;2(2):70.
- [12] Hosseini S, Foroutan H, Zeraatian S, Sabet B. *J Indian Assoc PediatrSurg* 2008;13(2):69.
- [13] Hosseini S, Zarenezhad M, Hedjazi A, Khazdooz M, Falahi S. *Ann Nigerian Med* 2012;6(1):22.
- [14] Romero P, Kroiss M, Chmelnik M, Königs I, Wessel LM, Holland-Cunz S. *Langenbeck's Arch Surg* 2011;396(7):1027-33.
- [15] Ali K. *Ann Pediatr Surg* 2010;6(2):81-8.
- [16] Hadidi A. *European J Pediatr Surg* 2003;13(3):176-80.
- [17] Elhalaby EA, Hashish A, Elbarbary M, Soliman H, Wishahy M, Elkholy A, et al. *J Pediatr Surg* 2004;39(3):345-51.
- [18] Teeraratkul S. *J Pediatr Surg* 2003;38(2):184-7.
- [19] Bhatia P, Joshi RS, Ramji J, Bachani M, Uttarwar A. *J Neonatal Surg* 2013;2(4):39.
- [20] Dehghan A, Hosseini M, Rahimi A, Zare S, Khazdooz M, Khoshnavaz R, et al. *J Hormozgan Univ Med Sci* 2014;17(1):1-7.
- [21] Aslanabadi S, Ghalehgholab-Behbahan A, Zarrintan S, Jamshidi M, Seyyedhejazi M. *Pediatr Surg Int* 2008;24(8):925-9.
- [22] Rouzrokh M, Jalali A, Samsami M, Zirakzadeh H, Heidari A, Fallah M, et al. *The J Shahid Sadoughi Uni Med Sci* 2011;19(3):350-8.
- [23] Zhang SC, Bai YZ, Wang W, Wang WL. *J Pediatr Surg* 2005;40(8):1307-11.
- [24] Teitelbaum DH, Cilley RE, Sherman NJ, Bliss D, Uitvlugt ND, Renaud EJ, et al. *Ann Surg* 2000;232(3):372.
- [25] Kim AC, Langer JC, Pastor AC, Zhang L, Sloots CE, Hamilton NA, et al. *J Pediatr Surg* 2010;45(6):1213-20.
- [26] Vahid Hosseini S, Mohammad Z, Sabet B, Sakineh F, Gholamzadeh S. *Oncol Gastroenterol Hepatol Rep* 2014;3(2):30.
- [27] Giuliani S, Betalli P, Narciso A, Grandi F, Midrio P, Mognato G, et al. *J Laparoendoscopic Adv Surg Tech* 2011;21(9):859-63.
- [28] Gosemann J-H, Friedmacher F, Ure B, Lacher M. *European J Pediatr Surg* 2013;23(2):94-102.
- [29] Stensrud KJ, Emblem R, Bjørnland K. *J Pediatr Surg* 2010;45(8):1640-4.
- [30] Dahal GR, Wang J-X, Guo L-H. *World J Pediatr* 2011;7(1):65-9.
- [31] Hosseini S, Gholamzadeh S, Zarenezhad M. *African J Paediatr Surg* 2014;11(1):94.