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ORIGINAL ARTICLE

URETHROCUTANEOUS FISTULA FOLLOWING SNODGRASS VERSUS TWO STAGE AIVAR BRACKA REPAIR OF DISTAL PENILE HYPOSPADIAS IN MALE CHILDREN: A RANDOMIZED CONTROL TRIAL

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ABSTRACT

Background: Hypospadias is the most common congenital malformation of the urethra with the prevalence of 1 in 200-300 live male births. The objective of this trial was to compare the frequency of urethrocutaneous fistula between Snodgrass and two staged Aivar Bracka repair of distal penile hypospadias in male children.

Material & Methods: This RCT was conducted in Department of Plastic & Reconstructive Surgery, Hayatabad Medical Complex, Peshawar, Pakistan from 1st June 2013 to 31st May 2014. 64 male patients were randomly allocated to two surgical procedures, 32 to experimental (Snodgrass) group and 32 to control (two stage Aivar Bracka) group. Age in years, age groups and presence of urethrocutaneous fistula were variables. Age in years was analyzed by mean, SD and range and other variables by count and percentage. McNemar chi-square test was applied to see the significance of difference between the experimental and control groups in terms of frequency of urethrocutaneous fistula at alpha 0.05.

Results: Mean age in experimental (Snodgross) group was 6.74 years±1.26 & in control (Aivar Bracka) group 6.71 years ±1.29. The urethrocutaneous fistula was present in three (9.38%, 80% CI 2.77-15.99%) cases in experimental (Snodgross) group and in six (18.75%, 80% CI 9.91-27.59%) cases in control (Aivar Bracka) group. McNemar chi-square test showed no significant difference between the experimental and control groups in terms of frequency of urethrocutaneous fistula.

Conclusion: The results are comparable for Snodgrass repair and two stage Aivar Bracka repair for distal penile hypospadias in male children in terms of frequency of urethrocutaneous fistula in our population.

KEY WORDS: Urethrocutaneous fistula; Snodgrass; Aivar Bracka; Hypospadias, Distal penile hypospadias.

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Preliminary: We have adopted an eight steps unpublished "Marwat Logical Trajectory of Research Process in Medical Research" presented by one of our authors Marwat M in organization of this project. It includes a sequence of logical activities of identifying the research problem, knowledge gap, research question, objective and hypothesis. Relevant facts and figures are accumulated (data collection) and analyzed to get information (data analysis) and interpreted to see if the tentative answer (hypothesis) is true or false? So that the objective is achieved, research question is answered, knowledge gap is filled and research problem is solved.

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INTRODUCTION

Background: Hypospadias is a congenital anomaly in which the meatus opens on the ventral surface of the penis due to the incomplete fusion of urethral folds.[1] Hypospadias is the most common congenital malformation of the urethra with affects 1 in 200-300 live male births.[2-3] The etiology of hypospadias is speculated to be the fetal exposure

to different chemicals with anti-androgen or estrogen like activity, which may interfere with normal hormonal signaling, such as dioxins and furans, polychlorinated biphenyls, organochlorine pesticides, phthalate esters, brominated flame-retardants and some heavy metals.[4] Hypospadias is categorized as glanular, subcoronal, distal penile, proximal penile and penoscrotal. There may be associated congenital anomalies like undescended testes, renal abnormalities and inguinal hernia, which make physical examination very important in these patients.[5]

Two staged Aivar Bracka (AB) repair is a relatively new technique, which gained tremendous popularity due to its versatility in that it can be used for any case of hypospadias with any degree of chordee. Complications with hypospadias surgery include fistula, meatal stenosis, dehiscence, recurrent ventral curvature and hematoma. A common complication with any hypospadias repair is urethrocutaneous fistula, which requires an additional surgery for its repair.[6] Comparative study showing Snodgrass repair superior to traditional Mathieu's repair state fistula rate 5.76% compared to 14.5%.[7] Aivar Bracka repair with meatal stenosis further increases the rate of fistula formation by 20 times in younger population.[8] The reported frequency of urethrocutaneous fistula with two stage AB repair is 17.3%[9] but no comparative study has been conducted on the same study population/ single trial.

Research Problem, Knowledge Gap & Research Question: There are many studies in global, regional, national and local literature showing separately the counts of urethrocutaneous fistula following Snodgrass and two stage Aivar Bracka procedure for repair of distal penile hypospadias in male children in different populations. But there are no studies comparing the two procedures in a single trial/ population. This is our Research Problem & Knowledge Gap. Which surgical procedure would be better in terms of frequency of urethrocutaneous fistula in our population? This is our Research Question. We would like to answer this question, fill up this gap and hence solve this problem.

Research Objective: The objective of this trial was to compare the frequency of urethrocutaneous fistula following Snodgrass versus two stage Aivar Bracka procedure for repair of distal penile hypospadias in male children.

Research (Null) Hypothesis: (H_0): The frequency of urethrocutaneous fistula is same in Snodgrass and two stage Aivar Bracka procedure for repair of distal penile hypospadias in male children in our population.

Significance and Applicability of the Trial: If the frequency of urethrocutaneous fistula with Snodgrass repair turns out to be lower than two stage Aivar Bracka repair for distal penile hypospadias in male children in our population, then it can be recommended relatively beneficial for the patients in terms of single stage procedure, decreased cost and reduced hospitalization. Further this trial will generate comparative base line data for future research in this domain for global, regional, national and local level researchers.

MATERIAL AND METHODS

This randomized control trial (RCT) was conducted at the Department of Plastic & Reconstructive Surgery, Hayatabad Medical Complex, Peshawar, Pakistan from 1st June 2013 to 31st May 2014.

A sample of 64 male children fulfilling the inclusion criteria was selected through consecutive non-probability sampling technique. All male children with distal penile hypospadias were eligible for inclusion. Those who were previously operated, cases of hypospadias cripples or patients with ambiguous genitalia, where sex differentiation was difficult were excluded from the trial. These age matched patients were randomly allocated to two surgical procedures, 32 to each of the experimental group and control groups. The experimental group was subjected to Snodgrass single stage hypospadias repair and the control group was subjected to two stage Aivar Bracka repair of hypospadias.

The proposal of the trial was approved by the Institutional Research & Ethics Committee. An informed consent was taken from the attendants of all the patients after explaining the trial protocol.

Procedure, Intervention & Follow up: All these cases were admitted. Detail clinical history and physical examination of all patients was performed. All surgeries were conducted under same general anaesthesia protocols. All the procedures were performed by plastic and reconstructive surgeons with at least five years post-fellowship experience.

In Snodgrass single stage hypospadias repair, neo-urethra formation over silicon catheter was performed followed by spongioplasty (approximation of the corpora spongiosa over the neo-urethra) in a single stage. The Aivar Bracka hypospadias repair was performed in two stages. In 1st stage, the urethral plate was incised to optimally correct the chordee and widen it which was covered with full thickness skin graft, harvested from prepucial, penile or retro auricular skin. In the second stage, which was performed after six months, the skin grafted urethral plate was tubularized over a silicone catheter.

All patients were given same per operative and postoperative antibiotics. All the patients in experimental group were discharged after three days. All the patients in control group were discharged in three days after first stage and three days after the second stage. All the patients were followed for development of urethrocutaneous fistula

according to a visit protocol at one week, two weeks and four weeks after completion of the concerned surgical procedure.

Data Collection Plan: Age in years and age groups were two demographic variables while presence of urethrocutaneous fistula was a single research variable. The data type for age in years was ratio (numeric), for age groups it was ordinal (3-6 and 7-10 years) while it was nominal (yes and no) for presence of urethrocutaneous fistula. The data for the presence of urethrocutaneous fistula was collected as a single observation at four weeks postoperative follow up.

Data Analysis Plan: Age in years was analyzed by mean, SD, minimum, maximum and range for each group separately. Age groups and presence of urethrocutaneous fistula were analyzed by frequency and percentage for each group separately. Interval estimate for presence of urethrocutaneous fistula in population was calculated as confidence interval for proportion at 80% confidence level by an on line statistical calculator[10] for each group separately. As there was no pretest data, so hypothesis testing was performed through posttest only analysis as recommended for experimental designs, comparing the frequency (count) of urethrocutaneous fistula in the two groups using McNemar chi-square test[11-12] at alpha 0.5 using an online statistical calculator GraphPad.[13]

McNemar Chi-Square Test: Chi-Square (χ^2) test of association has been used widely in literature for testing hypothesis like ours'. It is not a right practice. As the name implies, χ^2 test of association tells us relationship between two categorical (nominal/ ordinal) variables of the same group/ population. But here the question is to see for difference (not relationship) between the two groups/ populations for the same nominal variable. Here it is McNemar chi-square test which works. The variable is presence of urethrocutaneous fistula on nominal scale (yes/ no) and the two groups are experimental and control groups. The same 2 by 2 contingency table will be there, having four cells. It works on paired observations. Two cells a and d have concordant while b and c have discordant pairs. Cell a has concordant pairs having counts where both the groups have fistulae, cell d has counts where both have no fistulae. These counts, being equal for both the groups, give us no information to testify the null hypothesis. Cell b and c have counts where one group has fistulae and the other has not; these are discordant pairs used for analysis. Further χ^2 statistics is calculated through the difference between the observed count and expected count as usual for all types of chi-square tests. In our case there is only one degree of freedom, so Yates correction for continuity was also applied. (Table 1)

RESULTS

Out of a sample of 64 male patients, there were 32 (50%) patients in each of the experimental and control groups. Mean age in experimental (Snodgross) group was 6.74 years±1.26 (3-7) with a range of 4 years. Mean age in control (Aivar Bracka) group was 6.71 years±1.29 (3-7) with a range of 4 years. There were 22 (68%) children in age group 3-6 years and 10 (32%) children in age group 7-10 years in experimental (Snodgross) group. There were 21 (68%) children in age group 3-6 years and 11 (32%) children in age group 7-10 years in control (Aivar Bracka) group.

The urethrocutaneous fistula was present in three (9.38%, 80% CI 2.77-15.99%) cases and absent in 29 (90.62%, 80% CI 84.01-97.23%) cases in experimental (Snodgross) group, while it was present in six (18.75%, 80% CI 9.91-27.59%) cases and absent in 26 (81.25%, 80% CI 72.41-90.09%) cases in control (Aivar Bracka) group.

McNemar chi-square test was applied to see the significance of difference between the experimental and control groups in terms of frequency of urethrocutaneous fistula at alpha 0.05 as in Table 1. With p value of 0.3711, the null hypothesis was proved to be true and hence could not be rejected (it was accepted), showing no statistically significant difference between the two procedures in our population.

Table 1: Comparison of frequency of urethrocutaneous fistula following distal penile hypospadias repair in male children in two groups by McNemar Chi-Square test (n=64, 32 pairs)

Fistula in Control (Aivar Bracka) Group	Fistula in Experimental (Snodgross) Group		Total	Chi-square value	Degree of freedom	P-Value
	Yes	No		0.8000	1	0.3711
Yes	(a) 2	**(c)** 4	6			
No	**(b)** 1	(d) 25	26	Yates correction for continuity applied		H_0 accepted
Total	3	29	32			

DISSCUSION

An innovated procedure, the Aivar Bracka (two staged) repair has developed significantly the hypospadias surgery. Rickwood AM published his series of 367 cases in year 2000. He advocates a modern two stage procedure that may give an even caliber hairless neourethra with a vertically slit meatus and glans configuration. Not only did the result proved to be more beneficial than the single stage methods at that times, but also the procedure was relatively simple, reliable and repeatable.

Mansoor Khan, et al[14] published the largest series of hypospadias repairs of 428 cases in Khyber Pakhtunkhwa region stating Aivar Bracka repair being predominant in 76.2%, followed by Snodgrass repair in 20.8% cases. Irfan Ullah, et al[7] published a series of 139 cases and reported fistula rate following two staged Aivar Bracka repair of 17.3% in same center.

Obaidullah[15] published his 10 year report of hypospadias surgery from Peshawar, highlighting the benefits of the Bracka two stage repair in treating different types of anomalies with good results. These included normal looking slit like meatus (unlike MAGPI), one can deal with chordee, ventral surface is without scar and its application (unlike Snodgrass) in different anomalies, and hence requiring surgeons to master only one technique. There are many reasons for its wide spread popularity as being technically simple and greatly versatile with remarkable cosmetic outcomes. Overall, being uniquely versatile it can be used as a universal repair for almost any type of hypospadias. For a then trainee general plastic surgeon dealing with a still modest number of hypospadias patients, being able to master one otherwise simple procedure of repair and produce refined results in a broad spectrum of primary and re-operative cases is a good reason to adopt it.

Our study shows that mean age in Snogross technique was 6.74 ±1.26 years where as mean age in Aivar Bracka technique was 6.71±1.29 years. In Snogross technique 9.38% children had urethrocutaneous fistula while 90.62% children didn't had urethrocutaneous fistula where as in Aivar Bracka technique 18.75% children had urethrocutaneous fistula while 81.25% children didn't had urethrocutaneous fistula. Similar results were found in other studies as the reported frequency of urethrocutaneous fistula with two stage AB repair and Snodgrass repair was 23% and 7.2% respectively in different series but no comparative study has been conducted on the same study population/ single trial.

In our trial there was no statistically significant difference between the Snogross technique and two stage Aivar Bracka technique for distal penile hypospadias repair in male children in terms of frequency of urethrocutaneous fistula in our population as substantiated by McNemar chi-square test.

CONCLUSION & RECOMMENDATION

The results are comparable for Snodgrass repair and two stage Aivar Bracka repair for distal penile hypospadias in male children in terms of frequency of urethrocutaneous fistula in our population.

We would recommend similar but large sample and multicenter trials in different populations.

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CONFLICT OF INTEREST
Authors declare no conflict of interest.
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AUTHORS' CONTRIBUTION

The following authors have made substantial contributions to the manuscript as under:

Conception or Design:	HS, HG
Acquisition, Analysis or Interpretation of Data:	HS, HG, RK, MM
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All the authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.