



Original Article

EVALUATION OF THE OUTCOME OF IRPG 910 AND POLYPROPYLENE IN TERMS OF COSMESIS AND COST FOR SKIN CLOSURE IN CLEFT LIP SURGERY

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Abstract:

This prospective, comparative and interventional study was conducted in Bangabandhu Sheikh Mujib medical university in Dhaka and Center Point Hospital pvt .ltd in chittagong to evaluate advantage of using readily absorbable synthetic suture material IRPG 910 over non absorbable polypropylene in repair of cleft lip between time period of January 2003 to May 2004 in fulfillment of final part MS degree in pediatric surgery. A total of 26 patients with cleft lip (with or without cleft palate) who underwent operative procedure were included in this study. All the patients between the age of 3 months to 10 years having unilateral cleft lip with or without cleft palate were included while those with grossly deformed face or those associated with major anomaly were excluded.

Patients were divided into two groups, one group with 12(46%) as cases where IRPG 910 was used as a skin closure material and one group with 14(56%) as control group where polypropylene was used. In all the cases Milard's procedure was used except for one with central defect where linear closure was done, at the end of the study it is justified that IRPG 910 is as good as polypropylene as a suture material of choice in repair of cleft lip considering every pros and cons of both suture materials namely cost effectiveness, patient compliance, post operative complication and out come.

The most beneficial thing about using IRPG 910 over polypropylene was that it can avoid second anesthesia for stitch removal.

Introduction:

Cleft lip and palate has been a recognized congenital malformation from a very early human civilization as recorded in history. Illustrations appear as carvings on statues and in early manuscripts¹. These patients were stigmatized by social burdens and its evil connotation

let alone suffering they undergo. From time immemorial surgeons from every corner of world tried their best to commit themselves in restoring this defect back to its normality with minimum acceptable complication. For this it was found that the essence lies in proper reposition and use of appropriate suture material.

Materials and Methods:

Study Design

This was a prospective, comparative and interventional study done within the study period between January 2003 to May 2004.

Study Place

The study was carried out in the Department of Paediatric Surgery, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh and in the Centre point Hospital Pvt. Ltd., Chittagong, Bangladesh.

Target Group

All consecutive patients having unilateral cleft lip with or without cleft palate undergone surgical repair were included in the study. A total of 26 patients were included in the study. All patients of age group 3 months to 10 years and unilateral cleft lip with or without cleft palate were included in the study. Patients having unilateral cleft lip with grossly deformed face and unilateral cleft lip with major associated anomaly were excluded from the study.

Sample Collection

All the patients underwent primary repair of unilateral cleft lip in the Department of Paediatric Surgery, Bangabandhu Sheikh Mujib Medical University and also in Centre Point Hospital Private Ltd, in Chittagong, Bangladesh by estimating set parameters at preoperative and postoperative follow up. 2 patients were taken from BSMMU and 24 patients from Centre Point Hospital Private Ltd., Chittagong. As there was monthly cleft lip-palate treatment camp arranged at Centre Point Hospital

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Private Ltd., Chittagong, it was easy to accumulate patients from that hospital. Other patients from BSMMU were not included due to exclusion criteria.

Results :

We noted very satisfactory cosmetic result in all the 12 children sutured with Fast Absorption IRPG 910 subjects compared to that of polypropylene group. There was no significant difference in the cosmetic appearances of the wounds from either group. The scar had healed very well, with no indurations, smooth to touch and hardly visible. 16.7% patient in the IRPG 910 group above the age of 2 years and 21.4% in the polypropylene group expressed some pain in the wound and on digital evaluation no tenderness were demonstrated and all were psychological in origin. The main advantages of the IRPG 910 group children were no need for suture removal in contrast to that of polypropylene group. Out of 26 patients, General anesthesia was required for suture removal in 71.5% and the rest 28.5% of control group, stitches were removed after counseling without G/A and they were from higher age groups. Nearly all the patients / parents were preferred non-stitch removal. All the patients in the trial group left the hospital on the following day after

operation where as 64.3 % of the patients had to stay in the hospital for one week for stitch removal in the polypropylene group which is statistically very significant ($P < 0.01$). Though the cost of the suture material IRPG 910 is higher than that of the polypropylene, the overall costs involved for repeated visits, suture removal and anesthesia required in polypropylene group is quite higher (extra Tk.1000) than that of IRPG group.

Table-I
Socio-demographic profile

Profile	Number	Percentage
Age		
Gr-A: 3 months to <1 year	7	27
Gr-B: 1 to 3 years	6	23
Gr-C: 3 years to 10 years	13	50
Sex		
Male	15	58
Female	11	42
Socio- economic condition		
<5000 Tk.	22	85
>5000 Tk.	4	15

Table-II
Overall outcome of the series

Outcome	IRPG 910 group (n-12)		Polypropylene group (n-14)		Comments
	no.	%	no.	%	
Aesthetic					P<0.05
Excellent *	11	91.6	13	92.9	
Moderate **	1	8.4	1	7.1	P<0.05
Poor ***	0	0	0	0	
Discomfort (Pain / itching)	2	16.7	3	21.4	
Suture removal required	0	0	14	100	P<0.01
Anesthesia for stitch removal	0	0	10	71.4	P<0.01
Patients/ parents preference	12	100	2	14.3	P<0.01
Hospital stay					
2 days	12	100	5	35.7	P<0.01
7 days	0	0	9	64.3	P<0.01
P < 0.001					
Extra cost for stitch removal under General Anaesthesia (tk)	No need of stitch removal.			1000	
Costs involved per case for skin closure (in taka)	300	200			P < 0.01
Costs for hospital stay (tk)	200	700			P < 0.001

Test was done as the test of significance

* = Well healed, smooth, hardly visible.

** = Well healed with slight induration

*** = Healed with wide scar with stitch mark.

Discussion :

There is an increasing tendency now a day to treat / operate young children and babies on day care basis. Which significantly reduces clinical follow up to minimum but, at the same time suture removal is a great concern for both the surgeons and parents, researchers are looking for the cost effective and reliable techniques along with use of absorbable suture material for early disposal and a valid result. With this concept in mind, we planned our study to conduct a trial using Irradiated Polyglactin 910, which is fast absorbable suture material for skin closure in some selected cases and compare their outcome with that of closely matched traditional polypropylene group.

This study is a prospective study involving 26 very young patients having cleft lip with or without cleft palate. On the basis of suture materials used for skin closure in cleft lip repair, the patients were allocated into two groups. Fast Absorbable IRPG 910 suture were used in 12 subjects, and traditionally used non-absorbable polypropylene suture for the rest 14 patients. IRPG 910 is unique for its rapidity of absorption, less tissue reaction and the patients can be discharged on the following day after operation (2 days in the study). As there is no need for suture removal, our study population came for follow up at one week following operation without any detectable difference in outcome like tissue reaction, wound discharge/abscess compared to polypropylene. The financial and medical involvement for non-stitch removal in our series is minimal in the IRPG 910 group as shown in the results.

These findings are in concordance with the other studies stated in the literature, who have shown that significant savings in time and money with use of IRPG 910 by avoiding general anaesthesia for very young patients needing suture removal^{2,3,4}. Tandon have worked on skin and mucosal wounds stated with IRPG 910 and showed that the financial and organizational implications of avoiding suture removal are obvious³. Ekerot has shown that by using IRPG 910 the costs are reduced⁴.

It is a traditional practice to use polypropylene for skin closure in cleft lip repair⁵, which needs suture removal as also the control group in the series. Most of our patient in the polypropylene group (64.3 %) stayed in the hospital for a week until their stitch removal.

As shown in our study, there was no need for suture removal in the IRPG 910 group, which is very significant in saving time and money as well as probable complications of general anesthesia in such a young paediatric patients needing suture removal. Two patients in our study had anesthetic complication like aspiration and delayed recovery during suture removal. The added advantages of the IRPG 910 group was that there was very negligible tissue reaction on the operation sites with good wound healing which is almost equal to that of control group (91.6 % versus 92.9 %). The cosmetic values as observed in both the groups were identical as also found in other studies⁶.

This prospective study of 26 patients clearly demonstrates that the use of IRPG 910 is both safe and equally effective in skin closure in paediatric cleft lip repair is also in line with other study, who showed that absorbable and non-absorbable sutures are equally effective in oculoplastic surgery⁷. One interesting findings that came out from the present study was that, there was an unintended desire from the part of the patients and parents to use suture materials which needs no removal (85.7% versus 14.3%) and which can avoid second anesthesia in the young subjects.

There is a need for surgeons to be able to make a logical decision regarding which suture materials to be used in a given clinical situation, because the choice of wound closure materials may make a difference in wound healing and the ultimate functional and cosmetic result obtained⁸.

In our series, at 4th week we have seen that there were no stitches, as stitches fall off spontaneously. These findings are in concordance with the other studies in the literature^{3,9}. Tandon have shown that at day 16, more than two-third of IRPG 910 stitches fall off spontaneously. Shinohara, Matsuo & Kikuchi in their work on cleft lip, have shown that, Absorbable sutures are preferable to non-absorbable sutures for primary cleft lip repair with fewer complications¹⁰.

IRPG 910 is the fastest absorbing synthetic absorbable suture providing just the right strength at the start and rapid loss of tensile strength giving better comfort and convenience to patient¹¹. Suture begins to fall off as wound heals and hence there is no need for patient to come back for suture removal and so, no need for anaesthesia as suture removal is not required and needs less hospital staying eliminating the need for medical or paramedical care. So, it is cost effective

and gives less psychological trauma to the patient and parent by ensuring early home environment.

In our study, preoperative evaluation of spectrum of anatomical and functional difference was possible by measuring the parameters and with photographs.

Postoperative follow up measurement of parameters and photographs provided quantitative data about anatomical and aesthetical appearances, which was cosmetically acceptable.

However, the limitation of the study is that the sample size is very small (n=26) and follow-up time is very short, to draw any strong references from the outcomes and to find out the significance level for application in general. Larger study samples with multicentre trials along with meta analysis are very much needed to draw any recommendation for wide spread clinical application.

Summary :

This prospective study conducted in the department of paediatric surgery, B.S.M.M.U. & Centre point Hospital Pvt. Ltd., Chittagong, Bangladesh, between January 2003 to May 2004 with the aim and objective set to evaluate the outcome of IRPG 910 and polypropylene in terms of cosmesis and cost for skin closure in cleft lip surgery. Study population included 26 consecutive cleft lip patients. They were IRPG 910 group (n= 12 i.e., 46%) and polypropylene group (n= 14 i.e., 54%) for skin closure, repaired by Millard's technique.

Main outcomes were measured considering following parameters; incidence of tissue reaction, pattern of wound healing along with aesthetic view of the healed wound as reviewed after 3 months of follow up. The cost involved was calculated in terms of number of days in hospital, costing for suture removal under general anaesthesia

The subjects were closely matched in terms of age, sex, social class and types of cleft lip. Only inflammatory tissue reaction occurred as wound complication in 16.67% of IRPG 910 group and tissue reaction was 14.2% in polypropylene group (Inflammation was 7.1% and slight discharge from a stitch point was 7.1%). So, there was insignificant tissue reaction in both the groups

Scar contraction at 4th week follow up was observed in 8.3% cases in IRPG 910 group, which was also comparable to that of polypropylene (7.1%). At three

month, the wound healing was excellent in 91.7% cases with IRPG 910 group and was comparable to that of traditional polypropylene group (92.9%).

Loss of suture was so rapid that suture removal was unnecessary, eliminating the need for further medical and auxiliary follow up and care. No second anaesthesia was required as there was no need for suture removal and thus overall cost was calculated indirectly from money involvement which was relatively less than that of polypropylene.

Conclusion :

From our study it can be concluded that IRPG 910 is a useful suture material for skin closure in paediatric patient and it is cosmetically as good as polypropylene and cost effective in repair of primary cleft lip.

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