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Research Article

Randomized clinical trial of surgery versus conservative management of ureteropelvic junction obstruction with grade 3-4 hydronephrosis in infants: A preliminary report

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- Hydronephrosis
- Pyeloplasty
- Conservative management

Abstract

Context: Whether to conserve or operate in the subset of infants with Society for Fetal Urology (SFU) grades 3 and 4 hydronephrosis (HDN) due to ureteropelvic junction obstruction (UPJO), who have renal diuretic scan (RDS), either an obstructive curve with split renal function (SRF)>35%, or an equivocal curve irrespective of SRF is not settled.

Aim: To compare the short-term outcomes of surgery versus conservative management of UPJO with SFU grades 3-4HDN in infants.

Settings and Design: Randomized controlled trial.

Methods and Material: Twenty such infants with SFU grades 3-4 HDN due to UPJO in infants were randomized into 2 groups- Group A (surgery) (n=10) and Group B (conservative management) (n=10). Both the groups had ultrasonography (US) at 4 months postoperatively and RDS at 4-7 months postoperatively. The outcomes were compared in terms of SFU grade, drainage curve and SRF of the affected kidney. Based on these criteria, patients were divided into three categories- 'Improved', 'Status quo' or 'Deteriorated'. All the 3 'Deteriorated' category patients in the conservative management group were managed surgically and were further followed up for the outcomes.

Results: In Group A, 7 showed improvement and 3 remained status quo. In Group B, 2 showed improvement, 5 remained status quo and 3 deteriorated that necessitated delayed pyeloplasty; of these, 1 patient showed improvement and 2 remained status quopostoperatively.

Conclusion: As there is 30% failure rates in conservative management group compared to nil in surgery group, early pyeloplasty is a better choice in the infants who on postnatal evaluation have SFU grade 3-4 HDN due to UPJO and obstructive curve with SRF >35% or equivocalcurve on RDS.

ABBREVIATIONS

HDN: Hydronephrosis; SFU: Society for Fetal Urology; SRF: Split Renal Function; RDS: Renal Diuretic Scan; APPD: Antero-Posterior Pelvic Diameter; US: Ultrasonography; VUR: Vesico-Ureteric Reflux

INTRODUCTION

Uretero-Pelvic Junction Obstruction (UPJO) is defined as an obstruction of the flow of urine from the renal pelvis to the proximal ureter. It is the most common anatomical cause of Antenatal Hydronephrosis (ANH) and it's reported incidence is 1 in 500 live births screened by routine antenatal ultrasonography (US) [1]. Society for Fetal Urology (SFU) had divided ANH into 4 grades [2]. Most of the infants with SFU Grades 1 and 2 hydronephrosis (HDN) have split renal function (SRF)>35% on renal diuretic scan (RDS) and conservative management is recommended as they tend to resolve with time and usually only require US surveillance [2] For the SFU grades 3 and 4, those with SRF<35% and obstructive curve need surgical intervention, whereas SRF>35% and non-obstructive curve need

conservative management [3]. But many of the infants do not fall into these two groups; the management of this subgroup of patients is controversial. In few infants with SFU Grades 3 and 4 HDN or, antero-posterior pelvic diameter (APPD) >10mm with obstructive RDS curve, the SRF may still be >35%.There may be other infants having SFU Grades 3 and 4 HDN but the RDS curves are equivocal. Literature is ambivalent whether surgery or conservative management is indicated in such cases [4]. In this study, we would like to generate evidence-based data for optimal management of this subgroup of infants presenting with SFU grades 3 and 4 HDN on US.

MATERIALS AND METHODS

A randomized comparative study was designed from December 2014 to September 2016.

Patient Characteristics

The patients were selected from infants presenting to Pediatric Surgery OPD of our hospital, with SFU grades 3-4 HDN on US due to UPJO.

Inclusion Criteria

(i) RDS curve obstructive (t-t1/2 >20 minutes) and SRF >35%

(ii) Equivocal curve (t-t1/2 10- 20 minutes) irrespective of SRF.

Exclusion Criteria

(i) RDS curve obstructive (t-t1/2 >20 minutes) and SRF <35%

(ii) RDS curve non-obstructive (t-t1/2<10 minutes)

(iii) Bilateral HDN

(iv) Dilated ureter on US and associated vesico-ureteric reflux (VUR)

(v) Associated congenital anomalies of other systems

(vi) Single kidney

(vii) Palpable kidney

(viii) Febrile U.T.I.

(ix) Deranged kidney function tests.

Based upon the previous study of Palmer et al [5]. , the calculated sample size was 26. However, as the duration of study was less, sample size of convenience was taken, i.e., 20 cases. Randomization was done by computer generated random numbers that split the patients into two groups- A and B (allocation ratio: 1:1) with each group having 10 patients. Ethical clearance was taken from Institution Ethics Committee and written informed consents were taken from parents of all patients. In Group A patients, surgery (Anderson-Hyne's dismembered pyeloplasty) was performed by an anterior extra-peritoneal approach by the experienced consultants. Nephrostent and a tube drain were left in all cases. The nephrostent was removed on Day 7 after ensuring free flow by clamping it on Day 6. Median hospital stay was 8 (range: 7-10) days. Follow-up USto study SFU grading, renal dimensions (length and breadth), Antero-Posterior Pelvic Diameter (APPD), parenchymal thickness at mid-pole and pelvis to cortex ratio, were done by a single senior radiologist at 4 months for both the groups. Though we intended to repeat RDS at 4 months for all 20 patients, some had to even wait till even 7 months to get it done in another busy 'public' hospital; our hospital lacks the said facility. All patients were categorized according to RDS curve (obstructive, or equivocal) and SRF of the affected renal unit. Raw images were also inspected along with curves in all the cases as the reservoir effect of the dilated system affected the curves in SFU grades 3 and 4 HDN. Both groups were administered antibiotic prophylaxis during the period of the study.

Statistical analysis

All data are collected was entered in a MS Excel sheet & further evaluation was done by SPSS 17.0. Qualitative data between the surgical and conservative groups was compared by Pearson chi-square test and Fisher's exact test and quantitative data between the surgical and conservative groups was compared by Mann Whitney U test and t-test; $p < 0.05$ was considered significant.

Study outcome

Based on the follow-up US and RDS, the patients in both the groups, were categorized in one of three categories-Improved, Status quo or Deteriorated.

The patients were known to improve if one or more of the following criteria are noted:

1. Change in grade of HDN from SFU 3-4 to 1-2 at follow-up.

2. Change in RDS drainage curves from obstructed (t-t1/2>20 minutes)/ equivocal (t-t1/2 10- 20 minutes) to non-obstructive (t-t1/2<10 minutes) and/or improvement of ipsilateral SRF of >5% on follow-up RDS.

The patients were known to deteriorate if one or more of the following criteria are noted:

1. Change in grade of HDN from SFU 3 to 4 at follow-up.

2. Change of equivocal to obstructed drainage curve on follow-up RDS.

3. Ipsilateral SRF deteriorated>5%, even though there is no change in the drainage curve

4. The patient developed culture proven febrile UTI

5. The ipsilateral kidney that was not palpable initially became palpable on follow up.

All others not falling in any of the two above categories were kept in 'Status Quo' category.

All the 'deteriorated' category patients in the conservative management group had 'delayed' pyeloplasty.

Management was considered successful for all the patients in 'improved' and 'status quo' categories on follow-up, whereas it was considered 'failure' in patients who had deteriorated on follow-up.

Outcomes in the patients underwent 'early pyeloplasty' patients (Group A) were compared with those who had deteriorated on the conservative management and had 'delayed pyeloplasty' (Group B).

RESULTS

All these 20 infants had an antenatal diagnosis of HDN that was confirmed postnatally as SFU grade 3 or 4 unilateral HDN and on obstructive RDS curve with SRF >35% or those with equivocal RDS curves. Two patients had maternal history of mild oligohydraminos. The subjects in the two groups were evenly matched at the time of presentation as regards to median age, median weight, median SFU grade of HDN, mean SRF and incidence of equivocal viz-a-vizobstructive RDS curves (Table 1).

Group A (Surgery)

The median SFU grade on US at the time of presentation was 4 (range: 3-4) that improved to 2 (range: 1-2) postoperatively at follow-up. The mean SRF at presentation (48.7±7.4%) was statistically not significantly different from the mean SRF (48.3±4.3%) postoperatively (p=0.903). In 7 out of the 10 patients, non-obstructed curve was demonstrated on follow-up RDS.

Group B (Conservative management)

The median SFU Grade on US at the time of presentation was 3 (range: 3-4) that improved to 2 (range: 1-4) postoperatively at follow-up. The mean SRF marginally decreased from 46.7±6.2% at presentation to 45.0±9.4% on follow-up RDS (p=0.566).

Cross-over- Of the 10 patients in Group B, 3 (30%) crossed over to surgery because of deterioration in one or more criteria of the study. In 2 children, there was fall in SRF (>5%) on follow-up RDS, however, SFU grade had remained unchanged. In the third patient, a renal lump become palpable and there was increase in SFU grade from 3 to 4 (Figure 1).

Surgery versus Conservative management

At follow-up, the median SFU grades of the affected kidneys in Group A patients were 2 (range: 1-2) compared to 2 (range: 1-4) in Group B patients, which is statistically not significant (p=0.165).There was no statistically significant difference in the mean SRF between patients in the 2 groups at follow-up RDS (p=0.296).

The two groups were compared with respect to study outcome measure. In Group A, 7(70%) showed improvement, and 3 (30%) remained status quo-on short-term follow-up, whereas In Group B, 5 (50%) remained status quo, 3 (30%) deteriorated and 2 (20%) showed improvement on short-term follow-up. When the outcome of 7/10 (70%) improved patients in Group A were compared with 2/10 (20%) improved patients in Group B, it was statistically not significant (p=0.211).

There was 10/10 (100%) success rate in Group A compared to 7/10 (70%) in Group B, which was statistically not significant (p=0.211).

Failure rate in Group A was 0/10 (0%) compared to 3/10 (30%) in Group B, which was also statistically not significant (p=0.211).

The results of 'early' pyeloplasty in Group A (70% improved) when compared to 'delayed' pyeloplasty in 3 patients in Group B (33% improved) after follow-up were not statistically significantly different (p=0.510).

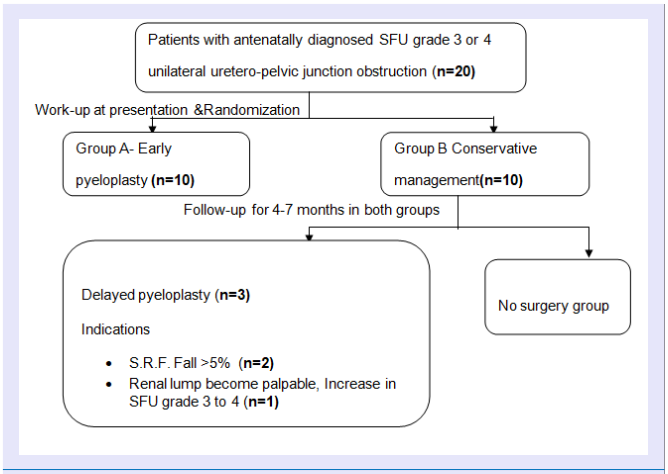

Figure 1 The breakup of total number of patients into various groups.

Table 1: Demographic characteristics of two groups at the time of presentation.

At presentation	Group A (Surgery)	Group B (Conservative)	p-value
Median age (months)	2.5 (range:1-11)	3 (range:1-11)	0.436
Median weight (kg)	4.4(range:3.2-9.2)	4.25 (range:3.4-9.1)	0.971
Median SFU grade of HDN	4 (range:3-4)	3 (range:3-4)	0.280
Mean SRF	48.7±7.4%	46.7±6.2%	0.527
RDS curve (Equivocal: Obstructive)	0:10	2:8	0.531

HDN: Hydronephrosis; SFU: Society for Fetal Urology; SRF: Split renal function; RDS: Renal diuretic scan

DISCUSSION

The postnatal management of asymptomatic unilateral HDN due to UPJO remains controversial and still there is no consensus among pediatric surgeons regarding the optimal timing of pyeloplasty. Even systematic reviews have failed to reach a definite conclusion regarding the best approach to treating these patients [6,7]. The fundamental issue that is debated is whether early pyeloplasty results in better preservation of or improvement in function than would be realized otherwise in the patient who undergoes a delayed operation at an older age.

In our study, in group A, the patients who underwent early pyeloplasty showed improvement in median SFU Grades as compared to Group B patients at follow-up, though this was statistically not significant (p=0.165).

There was no significant change in mean SRF at follow up in either of two groups and early surgical intervention was not associated with improved SRF on follow-up. Two patients in group B showed fall in split renal function >5% on follow-up and underwent delayed pyeloplasty.

In study reported by Palmer et al. [5], there was still no statistically significant difference in the mean SRF between patients in the 'surgery' and 'conservative management' groups

at 6 month and 1 year follow up. They considered reduction in SRF of more than 10% or the combination of increasing HDN and worsening drainage on RDS during conservative follow-up to select the patients for surgery.

Surgical intervention was associated with non-obstructive curve at follow up in 70% renal units, as compared to 20% in conservative group in our study. One child with equivocal curve at presentation in our series became obstructive on follow up with fall in SRF>5%, and he needed surgical intervention. Palmer et al. [5] reported that patients who were operated, the drainage pattern was significantly more likely to show no obstruction at 6 months and 1 year.

Babu et al., [8] reported that irrespective of initial SRF, early pyeloplasty in prenatally diagnosed SFU grade 3-4 UPJO leads to significant improvement of SRF, while delayed pyeloplasty leads to a marginal but, significant loss. Jain et al. [9] reported that there was no significant difference among the conservative and early surgery groups whether renal functions or distribution of outcome categories (improved, status quo or deteriorated) were compared.

The limitations of our study were the number of patients in each group was small and could not perform powerful analysis.

CONCLUSION

As there is 30% failure rates in conservative management group compared to nil in surgery group, early pyeloplasty is a better choice in the infants who on postnatal evaluation have SFU grade 3-4 HDN due to UPJO and obstructive curve with SRF >35% or equivocal curve on RDS. However, as the cohort of patients was very small, no statistical significance could be achieved as regards the success/ failure outcomes. A much larger multi-centric trial would be required to produce any meaningful results.

REFERENCES

1. Liang CC, Cheng PJ, Lin CJ, Chen HW, Chao AS, Chang SD. Outcome of prenatally diagnosed fetal hydronephrosis. J Reprod Med. 2002; 47: 27-32.
2. Nguyen HT, Herndon CD, Cooper C, Gatti J, Kirsch A, Kokorowski P, et al. The Society for Fetal Urology consensus statement on the evaluation and management of antenatal hydronephrosis. J Pediatr Urol. 2010; 6: 212-231.
3. Chertin B, Pollack A, Koulikov D, Rabinowitz R, Hain D, Hadas-Halpren I, et al. Conservative treatment of ureteropelvic junction obstruction in children with antenatal diagnosis of hydronephrosis: lessons learned after 16 years of follow-up. Eur Urol. 2006; 49: 734-738.
4. Sinha A, Bagga A, Krishna A, Bajpai M, Srinivas M, Uppal R, et al. Revised guidelines on management of antenatal hydronephrosis. Indian J Nephrol. 2013; 23: 83-97.
5. Palmer LS, Maizels M, Cartwright PC, Fernbach SK, Conway JJ. Surgery versus observation for managing obstructive grade 3 to 4 unilateral hydronephrosis: a report from the Society for Fetal Urology. J Urol. 1998; 159: 222-8.
6. Weitz M, Portz S, Laube GF, Meerpohl JJ, Bassler D. Surgery versus non-surgical management for unilateral ureteric-pelvic junction obstruction in newborns and infants less than two years of age. Cochrane Database Syst Rev. 2016: CD010716.
7. Weitz M, Portz S, Laube G. Primary non-surgical management of unilateral ureteropelvic junction obstruction in children: a systematic review. Pediatr Nephrol. 2017; 32: 2203-2213.
8. Babu R, Rathish VR, Sai V. Functional outcomes of early versus delayed pyeloplasty in prenatally diagnosed pelvi-ureteric junction obstruction. J Pediatr Urol. 2015; 11: 63.
9. Jain V, Agarwala S, Bhatnagar V, Gupta AK, Kumar R, Bal CS. Long Term Outcome of Management of Antenatally Diagnosed Pelvi-ureteric Junction Obstruction. Indian J Pediatr. 2012; 79: 769-73.

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