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Original Article

Quality of life of renal transplant donors

Sagar Koirala,[1] Pawan Raj Chalise,[2] Prem Gyawali.[2]

[1]Lecturer, Patan Academy of Health Sciences, (previously resident, TUTH)

[2]Department of Urosurgery, Tribhuvan University Teaching Hospital (TUTH), Kathmandu Nepal

Correspondence: Dr Sagar Koirala. MBBS, MS

Email: sagarkoirala85@gmail.com

Abstract

Introduction: End stage renal disease has a high rate of mortality and morbidity. Kidney transplantation remains the best treatment option in comparison to other forms of renal replacement therapy. Live related donor renal transplantation was started at TUTH in 2008. Compared to other established centers, the outcome of transplantation was comparable. Though there is considerable evidence showing that donors are able to return to their healthy life, quality of life (QOL) assessment using standardized questionaires has not yet been done in our centre. This study was carried out in order to compare QOL before and after donor nephrectomy.

Methods: Short Form 36 version 2 (SF36v2) was used to assess the quality of life of kidney donors. Interview was conducted just before and three months after donor nephrectomy. Eight domains of quality of life score were compared using SPSS 17.0. Kolmogorov Smirnov test was used to check normal distribution of data. Mean scores before and after donation was compared with paired t test. Multivariate linear regression analysis was done to find out variables predicting poorer outcome.

Results: Out of eight domains of quality of life, bodily pain, physical functioning and physical role limitation were decreased 3 months after donation. However, this did not have any impact on overall quality of life of donors. Increasing age was found to an independent predicter of poorer quality of life. However gender and donation status had no significance.

Conclusion: Quality of life of renal transplant donors was not affected by donor nephrectomy. Long term follow up and quality of study is required in order to assess the changes in physical health component with time.

Key words: Donors; end-stage renal disease quality of life; renal transplant.

Introduction

End-stage renal disease (ESRD), like many other chronic illnesses is associated with high rates of mortality and morbidity and imposes a huge economic burden on affected families as well as on the healthcare system.[1] Kidney transplantation remains the best treatment option for most patients with ESRD. As compared with dialysis, it provides better quality of life, increased degree of vocational rehabilitation, lower costs, and longer survival.[2-4]

A successful live donor renal transplantation service was stared in Nepal on 8 August 2008, in Tribhuvan University Teaching Hospital.[2] Since then, more than 170 renal transplants have now been performed in TUTH.[2] One-year patient survival, graft survival and secondary outcomes of kidney transplant recipients in TUTH are similar to the overall outcomes in larger, well established international centers.[1]

There is a considerable amount of evidence showing that kidney donors are able to return to a healthy life after unilateral nephrectomy.[2] The perioperative mortality after living kidney donation is 0.03% and morbidity, including

minor complications is less than 10%.[1] Because of its safety and excellent outcomes, the use of living donor kidneys has been strongly encouraged in literature.[2-6]

Although, the safety of living kidney donation has been well established, these studies are of a cross-sectional design comparing living donors with the general population, which includes subjects with diseases.[7-8] Meanwhile, only a few prospective studies examining the physical and psychosocial aspects of the donor's quality of life have been done.[6-9] A small part of the kidney donors experience a low Quality of Life (QOL) after kidney donation, particularly in terms of psychological functioning.[2, 10-12] Little is known about the pre-donation variables that adversely affect Quality of Life in such patients.[13] Furthermore, some donors report increased fatigability after donation, which may limit them in their participation in leisure activities. [13]

No study is available assessing the QOL among living kidney donors in Nepal. This prospective study is the first of its kind to evaluate Quality of Life among living kidney donors in Nepal.

Quality of life of renal transplant donors

It is essential that all the donors enjoy good QOL after surgery. After donor nephrectomy the patients can be discharged from the hospital within a week. They can resume their daily activities by two weeks. However, heavy works are restricted for 4 to 6 weeks. Sexual activities can be resumed in 4 to 6 weeks.

Besides physical wellness, social and psychological wellbeing is also important. It has been seen that psychological care before and after surgery is insufficient. SF36 is a standard questionnaire to evaluate quality of life and is well validated.[14]

Short form 36 version 2 (SF 36v2)

SF36v2 was developed to be brief, broad, generic measure of 8 domains of health that are important in describing and monitoring individuals suffering from a disease or illness.[15] It has 36 questions, which cumulatively gives score in 8 domains. These includes i) physical functioning (PF) ii) role participation with physical health problems, role physical (RP) iii) bodily pain(BP) iv) general health(GH) v) vitality vi) social functioning(SF) vii) role participation with emotional problem, role emotional(RE) and viii) mental health(MH)[16].

Methods

A prospective cross-sectional study was conducted among 45 consecutive living kidney donors presenting to Tribhuvan University Teaching Hospital from June 2013 to July 2014 for renal transplantation. Ethical approval was taken from Institutional Review Board of Institute of Medicine. All the patient underwent open donor nephrectomy.

Data was taken with the help of a structured questionnaire. The questionnaire consists of two parts. The first part consists of some basic donor information and demographic details. The second part of the questionnaire consists of the SF-36 questionnaire. SF-36, is a standardized questionnaire to measure the QOL.[17] It assesses eight health phenomena: (a) limitations on physical functioning because of health problems; (b) limitations in usual activities because of physical health problems (role-physical); (c) bodily pain; (d) general health perception; (e) vitality (energy and fatigue); (f) limitations on social functioning because of physical or emotional problems; (g) limitations on usual activities because of emotional problems (role-emotional); (h) general mental health (psychological distress and well-being).

After taking informed consent, subjects were asked to respond to the questionnaire and SF-36 survey. Interviews were individually conducted by the same investigator at two different time points: i) before open nephrectomy. ii) 3 months after transplantation.

Analysis was done using Statistical Package for Social Sciences (SPSS) version 17.0 (SPSS Inc., Chicago, IL, USA). Kolmogorov–Smirnov test was used to verify any departures from normality. In case of normal distribution, data was summarized in terms of means and standard deviation. Where data is found to be skewed, results were summarized as median and ranges. The change of QOL across time in study participants was determined using paired sample t test or Wilcoxon Signed Rank test depending on the normality of the distribution of SF-36 scores. Attempts have also been made to assess proportion of donors who have reduced QOL and have been compared with donors without reduced QOL scores on pre-donation variables. The association was assessed using a t-test (in case of continuous variables) or chi squares (in case of categorical variables). Variables have been entered in multiple linear regression analysis to determine independent predictor of poorer QOL. The level of significance has been chosen at 0.05.

Results

The youngest patient who underwent donor nephrectomy was 18 years and the oldest 62 years. Most of the patients were in the 20 to 50 years age group (51.1%), followed by those more than 50 years (28.9%). Mean age at donation was 40.74 with standard deviation of 12.6. Majority of donors were female (76%) compared to males (24%).

The physical as well as mental components of SF36 in patients before donor nephrectomy when broken down into 8 subcomponents, were in higher range with mean above 90 (except for general health) as these patients are selected for kidney donation only if they are both physically and mentally fit (table1)

Table 1: SF36 QOL scores before donor nephrectomy

Categories	Minimum	Maximum	Mean
Physical Functioning	90.00	100.00	99.67
Role Physical	87.50	100.00	99.03
Bodily Pain	100.00	100.00	100.00
General Health	65.00	100.00	84.22
Vitality	65.00	100.00	93.33
Role Emotional	83.33	100.00	97.04
Social Functioning	87.50	100.00	97.50
Mental Health	68.75	100.00	92.08
Overall	88.19	98.61	94.02

Table 2: SF 36 QOL scores after donor nephrectomy

Categories	Minimum	Maximum	Mean
Physical Functioning	80.00	100.00	97.00
Role Physical	62.50	100.00	95.14
Bodily Pain	50.00	100.00	92.50
General Health	60.00	100.00	83.89
Vitality	65.00	100.00	96.00
Role Emotional	50.00	100.00	98.33
Social Functioning	62.50	100.00	96.39
Mental Health	68.75	100.00	94.30
Overall	73.61	97.92	93.05

After 3 months of donor nephrectomy, minimum scores in each category has decreased with maximum decrease of score in bodily pain (Table 2). However the mean score in each category after nephrectomy is still above 90 except for general health (Table2).The physical component has more changes in mean score before and after surgery (Figure 1).

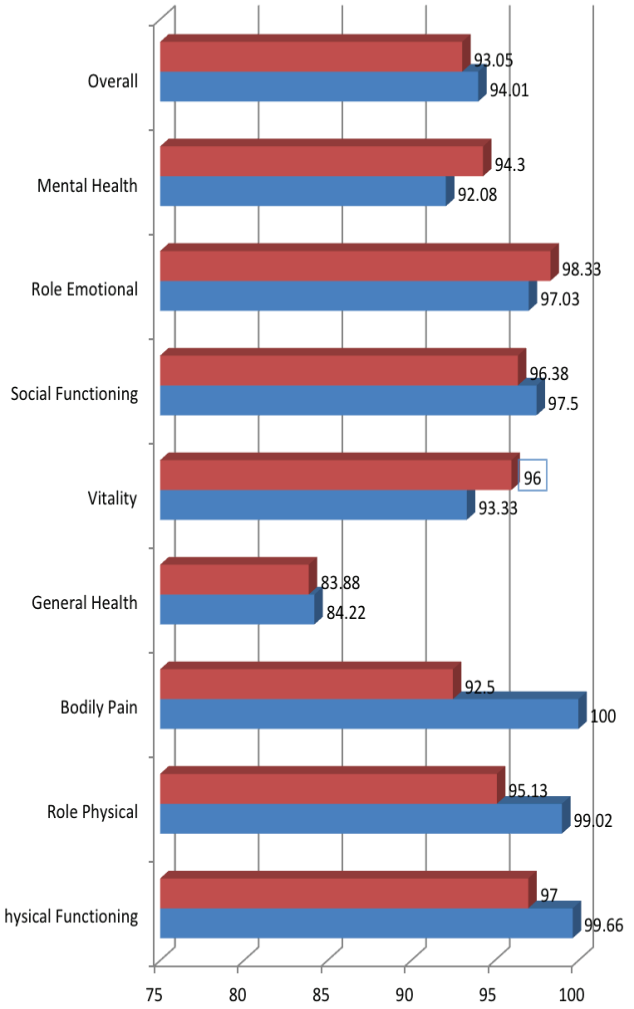

Figure 1: Comparison of mean SF 36 scoring on several

categories before and after donor nephrectomy

Table 3: Comparison of QOL scores across several categories of SF 36 using paired T-test, before and after donor nephrectomy

Categories	Mean before Nephrectomy	Mean after Nephrectomy	P value
Physical Functioning	99.66	97.00	.001
Role Physical	99.02	95.13	.003
Bodily Pain	100.00	92.50	.001
General Health	84.22	83.88	.880
Vitality	93.33	96.00	.153
Social Functioning	97.50	96.38	.406
Role Emotional	97.03	98.33	.364
Mental Health	92.02	94.30	.283
Overall	94.01	93.05	.300

Patients after donor nephrectomy experienced significant bodily pain even after 3 months of surgery limiting their physical functioning (P = 0.001) and physical participation (P = 0.003). (Figure 1, Table 3) The physical health component was significantly decreased with no significant change in mental health component. However overall quality of life was not significantly different from pre donation state. (Table1, 2,3)

Using multivariate linear regression model for predictors of quality of life, only age was found to significantly correlate with poorer QOL (β = -0.27, P = 0.015). Gender and donation status did not predict poorer QOL.

Discussion

The response rate of this study has been 100% as the patients were interviewed before donor nephrectomy during their visits in OPDs or at the time of admission. Since the donors are closely related to the recipient, who are on regular medical follow up at our center, contacts could be easily made for interviews after donation. The other reason is short term follow up done in this study. Since the pre and post donor quality of life was evaluated in cross over design of the study, various confounding bias is eliminated.

Donors in this study were selected according to Amsterdam criteria after thorough physical and mental health checkup. Hence pre donation quality of life was excellent with no compromise in physical or mental component. Donors in this study did not have overall change in the quality of life before and after donation. However they complained of bodily pain persisting at 3 months after donor nephrectomy. They also had limitation in their physical functioning and role. These limitations did not have consequence in overall quality of life. As this study was done on short term follow up at three months, the bodily pain and physical role and function limitation experienced might be attributed to the post-operative pain. However, long term follow up studies show no difference in bodily pain, physical role limitation or functioning. [6] If the donors are followed up in long term, the physical health component is likely to improve to the point where no significant difference is seen. Increasing age of the patient was found to be independent predicting factor for poorer quality of life in multivariate linear regression model. Gender and donation status had no effect on quality of life.

A study reported from Nepal in 2008 showed that post-donation SF-36 scores of the donors were not statistically significantly different from those of the control group except in one out of eight dimensions, which was physical role. This was attributed to development of other comorbidities.[18] However, age, gender and donation status did not affect quality of life in this study.

A follow up of 35 patients who underwent laparoscopic nephrectomy with SF36 questionnaire and 6 minute walk test before and after 1 month revealed that the patients resumed to baseline exercise capacity but not to baseline physical general health.[19]

The evaluation 48 donor-recipient couple before and 4 months after renal transplantation and found no difference in quality of life of donors. However the quality of life of recipients was improved.[20]

Other studies conducted regarding quality of life of donors using SF 36 have compared between the donors and non-donors.[6] Mostly conducted with SF 36 survey questionnaire, the scores of donors and non-donors in these studies are comparable. [3, 10, 21-22] The same studies have also shown that donors have positive donation related attitude, and if given opportunity would donate again.

Conclusion

Quality of life of renal transplant donors is not affected by donor nephrectomy. Long term follow up and QOL study is

required in order to assess changes in various components of QOL with time.

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Original Article

Randomized study comparing safety and efficacy of one shot versus serial metal telescopic dilation technique in percutaneous nephrolithotomy

Ganesh Bhakta Acharya, Anil Shrestha, Hari Bahadur KC, Robin Bahadur Basnet, Aravind Kumar Shah, Paras Mani Shrestha

Department of Urology, National Academy of Medical Sciences, Kathmandu, Nepal

Correspondence: Dr. Ganesh Bhakta Acharya, Department of Urology, National Academy of Medical Sciences, Bir Hospital, Kathmandu, Nepal.

Email: ganeshnmc@yahoo.com

Introduction

Percutaneous nephrolithotomy is an efficient method for the management of various types of renal stone disease. The procedure is usually achieved through a percutaneous needle access to the renal collecting system under fluoroscopic guidance. This is then followed by nephrostomy tract dilation. Dilation of the tract may be achieved by many different techniques such as amplatz sequential fascial dilators, metal telescopic dilators and balloon dilators.[1]

Balloon dilation is regarded as the most modern and safest method with a low bleeding complication; however, its high cost precludes its routine use for every patient, especially in developing countries. Furthermore, in patients with renal scars, the application of a balloon dilator system is difficult with higher failure rates.[2]

Dilation with the amplatz set, which leads to the waste of 10 disposable dilators for each procedure, has intermediate cost similar to the cost of pneumatic dilation. Dilation with alken system is the least expensive procedure. But both of these multiple incremental dilation techniques are more time consuming and require longer exposure to fluoroscopy than balloon dilation. Furthermore, incremental dilator system such as alken and amplatz are associated with risk of working guidewire displacement, buckling and development of a false passage. The result could be hemorrhage, collecting system perforation and even operation failure. In some studies, as many as one third of patients needed blood transfusion when tract dilation was based on these methods.[3, 4]

To reduce the risk of access complications and improve the access and radiation exposure times, various approaches have been improved.[5, 6] These dilation systems which comprise of single step acute dilation named "one shot" or "single shot" technique include a single dilation of the nephrostomy tract with a desired amplatz dilator. These dilation systems are rapid, single step access systems that are supposed to decrease the chance of access failure, time of operation and radiation exposure. Moreover, one shot dilation technique has been shown to be as safe and effective as metal telescopic dilation even in patients with a history of ipsilateral open renal surgery.[7] However due to the lack of sufficient investigations with a large enough sample size, their application has not yet become universal.

Our aim in this study was to compare the safety and efficacy of single shot dilation of the nephrostomy tract by amplatz dilator and serial alken metallic telescopic dilation technique. We also compared the feasibility of single shot technique in patients with previous open stone surgery.

Patients and Methods

This prospective randomized study was carried out on patients who underwent PCNL for renal stone disease in Department of Urology, National Academy of Medical Sciences, Nepal from January 2015 to December 2015. The purpose of the study was explained to all the patients and their written informed consent was obtained. This study was approved by Institutional Review Board (IRB). Inclusion criteria included all patients above 18 years of age who were posted for PCNL for renal calculus disease. Patients undergoing bilateral simultaneous PCNL for the bilateral stone on the same sitting, patients with nephrostomy tube

in situ and patients with more than single access tract were excluded. Admissions were done a day prior to surgery and randomized by computer generated tables into two groups; Group A: alken metallic telescopic dilators and Group B: amplatz "One Shot' technique.

The surgery was performed under regional or general anesthesia. All the surgeries were performed by experienced consultant urologist in the institution. First the patient was kept in lithotomy position and 5 F or 6 F ureteral catheter was placed in desired ureter under fluoroscopic guidance with 19 F cystoscope which allows the injection of contrast or saline. Thereafter, the patient was changed to the prone position. In each group the puncture of collecting system was achieved by 18-gauge needle under fluoroscopic guidance. The return of urine on removal of stylet confirmed entrance into the collecting system. A 0.035-inch straight tip hydrophilic guidewire was then inserted and skin incision of 10 mm was made on the puncture site. Then fascial dilation was done by 9 F fascial dilator. In Group A patients this step was followed by insertion of the Alken guide and of the serial telescopic dilators from 9 F to 27 F. Then 24-26 F Amplatz sheath was passed and dilators were removed. In Group B a single reusable 24-26 F Amplatz dilator was advanced over an Alken guide which was followed by passage of 24-26 F Amplatz sheath and the dilator was removed.

Demographic data as well as intraoperative information such as access time (the time elapsed between insertion of guide wire after puncture into the collecting system and the placement of Amplatz sheath) and success rate (complete dilation to desired caliber and successful nephroscope entrance into collecting system) were recorded. Once the stone was localized pneumatic lithotripsy was performed for stone fragmentation. Patient requiring more than one tract for clearance of stone was excluded from the study.

Postoperative hemoglobin concentration and hematocrit level were measured four and 24 hours after the surgery. The rate of hemoglobin drop was compared with the preoperative hemoglobin level. Presence of fever/ sepsis as well as number of blood transfusion or need of angioembolisation were also recorded. Complications were also noted.

Patients were followed up after one week to look for any features of delayed hemorrhage or urinary leak from the percutaneous site.

Finally, presence of complication after PCNL were graded as Modified Clavien-Dindo Classification.[8]

Statistical analysis was performed using chi-square, student's t-test and z test. The level of significance was defined as $p<0.05$. All data were analyzed with SPSS version 17 software (Chicago, IL).

Results

Out of 138 patients of renal stone enrolled in the study, 38 patients were excluded due to multiple tract. Remaining 100 hundred patients, 50 in each group, were finally analyzed. These groups were similar in terms of age and sex, and there were no significant differences in preoperative variables such as mean stone size, location and side (Table 1).

Table 1. Preoperative variables of patients

Parameters	Group A (n=50)	Group B (n=50)	p-Value
Mean Age (years)(range)	38.7(20-72)	39.5(18-75)	0.587
Male/female	32/18 (64%/36%)	36/14 (72%/28%)	0.389
Side(R/L)	20/30 (60%/40%)	21/29 (58%/42%)	0.979
History of ipsilateral open stone surgery	6(12%)	6(12%)	1.00
Stone location			0.548
Renal pelvis	24 9	27 8	
Staghorn	11 4	11 3	
Lower calyx	2	1	
Middle calyx			
Upper calyx			
Stone size(mm)	20±11	19±7	0.60

Group A, alken serial dilation; Group B, single shot dilation

The mean access time(mins) was shorter in group B than group A (5.89 vs 4.98) but not statistically significant($p=0.061$). Success rate was similar in both the groups (96% vs 94%; $p=0.64$). Dilation related intraoperative complications were higher in group A (26% vs 14%; $p=0.13$) but not significantly different (Table 2).

Table 2. Intraoperative variables

Parameters	Group A (n=50)	Group B (n=50)	p-value
Entrance calyx			0.211
Lower	23(46%)	19(38%)	
Middle	19(38%)	27(54%)	
Upper	8(16%)	4(8%)	
Mean access time (min)	5.89±2.67	4.98±2.0	0.061
Success rate	48(96%)	47(94%)	0.64
Under dilation	6(12%)	2(4%)	0.14
Over dilation	5(10%)	4(8%)	0.72
Collecting system perforation	2(4%)	1(2%)	0.55

Group A, alken serial dilation; Group B, single shot dilation

Under dilation, amplatz sheath within the kidney but not in the desired calyx;

Over dilation, amplatz sheath beyond the desired calyx but still inside the kidney;

Collecting system perforation, amplatz sheath passed beyond the calyx and outside of the kidney

Table 3. Postoperative values and outcome of procedure

Parameters	Group A (n=50)	Group B (n=50)	p-value
Mean postoperative Hb drop(g/dl)	1.27±1.10	1.71±1.41	0.086
After 4 hrs.	1.46±1.32	1.74±1.35	0.30
After 24 hrs.			
Blood transfusion (%)	1(2%)	4(8%)	0.16
Hydrothorax (%)	1(2%)	1(2%)	1.0
Urinary leak (%)	1(2%)	1(2%)	1.0
Postoperative urinary tract infection (%)	9(18%)	7(14%)	0.58
Mean hospital stays± SD(days)	3.30±1.61	3.24±1.27	0.837

Group A, alken serial dilation; Group B, single shot dilation; Hb, Hemoglobin

Table 3 summarizes the postoperative values and outcomes of procedure. Mean hemoglobin drop in both the group were not significantly different. Five patients received blood transfusion in the postoperative period (1 in group A and 4 in group B). There were three patients in group A and four patients in group B who were readmitted after discharge for hematuria and all of them recovered well with conservative management. None of the readmissions required blood transfusion. Postoperative UTI (9 patients in group A and 7 patients in group B), postoperative hydrothorax (1 patient in each group) was managed by antibiotics and pleural tapping respectively. Two patients developed urinary leak (one patient in each group), which were managed by DJ stenting and Foley catheterization. There was no visceral or vascular injury in either of the group. Residual stones were present in 14 patients (11 in group A and 3 in group B) and ancillary procedures, such as shock wave lithotripsy or re-PCNL were performed. Hospital stay was similar in both the groups (3.30±1.61 vs 3.24±1.27 days; p=0.837). No significant difference in complications between the two groups (Table 4) was noted.

Table 4. Complications as per Modified Clavien Dindo Classification

Parameters	Group A (n=50)	Group B (n=50)	p-value
Grade			
None	21(42%)	12(24%)	0.164
1	20(40%)	22(44%)	
2	6(12%)	8(16%)	
3A	3(6%)	8(16%)	
3B	-	-	
4	-	-	
5	-	-	

Group A, alken serial dilation; Group B, single shot dilation

Six patients in each group had history of previous renal surgery but none of them failed the dilation technique. Two patients had over dilation in group B which was not statistically significant. Overall complications and surgical outcome was not significantly different between these subgroups.

Discussion

PCNL is the gold standard treatment for the management of large renal stones (>2 cm) that has revolutionized surgical treatment, with minimally invasive procedures now being preferred over open surgical approaches. The creation and dilation of nephrostomy tract is the key step of PCNL, which is performed basically with three dilation methods; metal telescopic Alken dilators, incremental Amplatz dilators or balloon dilators. All of these techniques help in creating the nephrostomy tract over which an Amplatz sheath of desirable size(28-34 F) can be passed.[2,9] Balloon dilator is considered the most safe method for one step tract dilation; however its high cost precludes its use in many centers with limited resourses.[2,10] Besides it has got higher failure rate in patients with previous renal scars.[2] Amplatz dilator and/or metal Alken dilator system is the second best option where balloon dilator system is not feasible or available for tract creation; however, their incremental nature can be a problem especially in terms of prolongation of access time, radiation exposure and possibility of tract displacement.

To improve the dilation results, some authors have proposed single-increment dilation and demonstrated its safety and feasibility.[11, 12] Travis and colleagues[12] performed this technique in dogs to investigate the effects of single-increment renal tract dilation to 24 F and compared with conventional techniques. They compared the effects of this technique with those of multi-incremental or balloon dilation and found no difference in tissue damage either immediately or at 6 weeks. Aminshariffi et al[13] demonstrated that although the one stage tract dilation technique reduced radiation exposure and access time in the short term, it may cause more parenchymal damage than the gradual dilation technique.

Rusnak and coworkers[11] described a dilator composed of an 8F polyurethane tube cemented to a gradually tapering polyurethane dilator of the desired size (10F to 34F) that was passed over a guidewire into the pyelocaliceal system, with the 8F portion entering the proximal part of the ureter. Frattini et al[5] described a single dilation with a 25 F or 30 F Amplatz dilator advanced over an Alken guide or an 8 F dilator. The results were comparable with current standard techniques and fluoroscopy time and cost were significantly reduced.

Our technique was performed using available reusable instruments and it was not based on passing the port of the dilator into the ureter thus being feasible even in the presence of stones that completely occlude the calyx, preventing the passage of any instrument into the renal pelvis. We compared one- shot technique with conventional metal telescopic dilators. Our results clearly show that the one-shot procedure is feasible and effective.

Open Nephrolithotomy leads to retroperitoneal scars around the kidney that may adversely affect introduction of access needle and prevent proper dilation of the tract, necessitating the use of metal and balloon dilators.[14, 15] Previous studies reported a higher failure rate for PCNL in those patients with previous open intervention.[14, 16] Frattini et al[5] has reported that one shot dilation was unsuccessful in two patients who had history of previous open stone surgery. Similarly, in Falahatkar et al[7] study one-shot dilation was unsuccessful in three patients, out of which two had history of previous open renal surgery. They noted that these features represented real contraindication to one-shot technique. Sofikerim et al[17] reported that kidney with previous open surgery can be punctured easily by the access needle. They used amplatz dilators for tract dilation and did not report any technical difficulty in their study. Three (6%) of our cases of one-shot technique were unsuccessful. The causes in these patients were, guidewire displacement during the process of dilation, tract lost and under dilation. None of the patients had history of previous renal surgery. In our study, there were six patients in group B who had history of ipsilateral stone surgery but none of them had failed one-shot technique.

Mean access time, success rate, perioperative complications, mean hemoglobin drop were not significantly different in both the groups with history of previous open stone surgery which demonstrates that one shot technique is equally effective and safe in patients with history of open stone surgery. Similarly, Amjadi et al[18] also reported that one shot procedure was feasible in patients with previous open nephrolithotomy. It was safe and effective as the telescopic procedure, with significant reduction in X-ray exposure.

Single shot dilation is safe and effective in almost every adult population.[7 10, 19, 20] One shot dilation did not lead to more hemorrhagic complications than alken serial dilation techniques. In our study, four (8%) patients required blood transfusion which is comparable with other results.[5, 7] None of the patients required conversion to open surgery or angioembolisation. Complications were graded in terms of Modified Clavien-Dindo classification in both the groups, and results were not significantly different.

Conclusion

One-shot dilation is safe and effective like metal telescopic

dilation in all adults' patients. It has also been effective and safe in patients with a history of ipsilateral open renal surgery. However, to come to a definite conclusion a further study is warranted with large number of samples.

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