Minilaparoscopy versus Standard Laparoscopic Donor Nephrectomy: Comparison of Safety, Efficacy and Cosmetic Outcomes in a Randomized Clinical Trial.

Nasser Simforoosh, Seyed Hossein Hosseini Sharifi, Reza Valipour, Behzad Narouie, Mohammad Reza Kamranmanesh, Mohammad Hossein Soltani*

Purpose: This study was conducted to compare safety, efficacy and cosmetic outcome between standard laparoscopic live donor nephrectomy (sLDN) and minilaparoscopic donor nephrectomy (mLDN) in a randomized clinical trial.

Materials and Methods: From March 2012 to June 2013, 100 consecutive kidney donors were randomly assigned to two equal groups for laparoscopic donor nephrectomy. mLDN: Six to eight centimeters Pfannenstiel incision was made slightly above pubis symphysis and 11 millimeters trocar was fixed through exposed fascia using open technique. Five mm port was placed under direct vision at the umbilicus for camera insertion and two 3.5 mm ports were placed in subxiphoid and paraumbilical area.
sLDN: Ten mm port was placed at umbilicus using open access technique for camera insertion. Five mm trocar for grasping and 11 mm trocar for vascular clipping were placed at subxiphoid and paraumbilical areas under direct vision, respectively. The second 5 mm trocar was placed in suprapubic area. Cosmetic appearance was assessed three months after surgery by using the Patient Scar Assessment Questionnaire (PSAQ).

Results: Demographic data of the patients was not significantly different between two groups. Total operative time and ischemic time was nearly similar in both groups (104 ± 21 vs. 114 ± 24 min; P = .327 and 4.03 vs. 4.07 min; P = .592). There were no cases of conversion to open surgery. Mean hospital stay was similar between the two groups [2.1 (2-5) vs. 2.4 (2-5) days; P = .346]. Kidney graft function assessed by serum creatinine values (mg/dL) of recipients, was equivalent in both groups (1.58 vs. 1.86: P = .206). Mean appearance score (34 vs. 29) and consciousness score (22 vs. 18) in PSAQ showed significantly better results in the mLDN group.

Conclusion: Our experience in this study revealed that peri- and post-operative findings were comparable between sLDN and mLDN, but mLDN has significant better cosmetic appearance than standard laparoscopic approach.

Keywords: nephrectomy; methods; adverse effects; laparoscopy; tissue and organ harvesting.

INTRODUCTION

With increasing need and desire for kidney transplantation, waiting lists for cadaveric kidney donors continue to grow and live organ donation has gained much more attention. Postoperative pain and morbidity and cosmetic issues maybe some of major disappointing factors for potential kidney donors, thus, every effort should be encouraged for reducing disinclination of living donors.
Laparoscopic donor nephrectomy (LDN) has grown to be the preferred surgical technique in most transplant centers after the first report by Ratner and colleagues.[1,2] Several studies showed that LDN is associated with less hospital stay, better cosmetic results and similar complications and long term graft survival compared to open donor nephrectomy.[3,4] Laparoendoscopic single-site (LESS) donor nephrectomy is an evolving technique for retrieval of the kidney but with confounding effects on cosmetic results.[5] Natural orifice translumenal endoscopic surgery (NOTES) has shown encouraging results but is applicable in minority of cases.[6] minilaparoscopic surgery is an attempt to perform a less invasive surgery and enhance cosmetic result of laparoscopic surgery. Recently, we reported initial series of minilaparoscopic live donor nephrectomy (mLDN)[7] and results of the aforementioned study encouraged us to compare results of minilaparoscopy with conventional LDN in a randomized trial study.

MATERIALS AND METHODS

From March 2012 to June 2013, 100 consecutive kidney donors were randomly assigned to two equal groups for laparoscopic donor nephrectomy: standard LDN (sLDN) and mLDN. Simple randomization method was used. All patients signed written informed consent before the study and the ethical committee of Iranian Urology and Nephrology Research Center approved the study design.
Regarding the power factor of 80% for the study and 95% confidence level, a sample size of 100 cases was

Shahid Labbafinejad Medical Center, Urology and Nephrology Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran.
*Correspondence: Shahid Labbafinejad Medical Center, Urology and Nephrology Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran.
Tel: +98 21 2256 7282 & Fax: +98 21 2256 7282. E-mail: mhsoltani60@gmail.com.
Received June 2015 & Accepted August 2015.

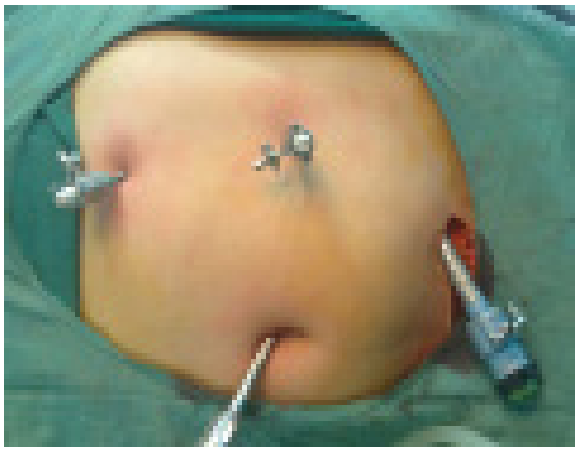

Figure 1. Trocar configuration in minilaparoscopic donor nephrectomy.

calculated. Computed tomography (CT) angiography was performed in all donors preoperatively. Donors with multiple renal arteries and right side donor nephrectomy were excluded from this study. High body mass index (BMI greater than 29) was not an exclusion criterion in our study. All operations were performed under general anesthesia and in modified left flank position.

Technique of Trocars Insertion for mLDN

Six to eight centimeters Pfannenstiel incision was made slightly above pubis symphysis and 11 millimeters trocar for suctioning, cauterizing, and vascular clipping was fixed through exposed fascia using open technique. After Peritoneal insufflations, 5 mm port was placed under direct vision at the umbilicus and used for insertion of the camera and two 3.5 mm ports that were placed in subxyphoid and paraumbilical area for grasping and scissoring, respectively. All trocars at visible areas of abdomen were 3.5 millimeters (**Figure 1**).

Technique of Trocars Insertion for sLDN

Ten mm port was placed at umbilicus using open access technique for camera insertion. After peritoneal insufflations, 5mm trocar for grasping and 11 mm trocar for vascular clipping were placed at subxyphoid and paraumbilical areas under direct vision, respectively. The second 5 mm trocar was placed in suprapubic area (**Figure 2**).

Figure 2. Trocar configuration in standard laparoscopic donor nephrectomy.

Table 1. Patient Scar Assessment Questionnaire consists of five subscales and range of score in each items.

Variables	Number of Scored Items	Minimum Score	Maximum Score
Appearance	9	9	36
Consciousness	6	6	24
Symptom	7	7	28
Satisfaction with appearance	8	8	32
Satisfaction with symptoms	5	5	20

Technique of LDN

The white line of Toldt was incised and descending colon mobilized medially and splenorenal and renocolic ligaments were dissected. The left ureter and the gonadal vein were dissected from surrounding tissues while preserving peri-ureteral tissues. The renal vein was dissected distal to the gonadal vein. Bipolar cautery was used for coagulating of adrenal and lumbar veins. Left renal artery was dissected and exposed from its origin. After renal hilar dissection, the kidney attachments to the abdominal wall were released. The renal artery was clipped using one Hem-o-lock (10 mm) and one titanium clip and the renal vein was clipped using two Hem-o-lock clips (10 and 12 mm) and finally one Hem-o-lock clip (12 mm) was used for ligation of ureter.[8] The kidney was hand extracted from the previously opened Pfannenstiel incision and then incision closed anatomically.[9] A Penrose drain was inserted and mini-port sites remained unsutured and only Steri-Strips were applied. Cosmetic appearance, operating time, hospital stay, complications and graft survival were assessed in all patients in both groups. Cosmetic results were assessed in all patients, three months after surgery by using the Patient Scar Assessment Questionnaire (PSAQ), a reliable and valid measure of the patient's perception of scarring and developed for plastic and reconstructive surgery (**Table 1**).[10]

Statistical analysis was performed using Statistical Package for the Social Science (SPSS) version 19 (SPSS Statistics for Windows, Version 19.0. Armonk, NY: IBM Corp., Released 2010) using the independent t-test for quantitative data and the chi-square test for qualitative variables. A P value of $< .05$ was considered as statistically significant.

RESULTS

Mean age of patients in mLDN and sLDN was 27.4 (20-38) years and 28.2 (21-43) years, respectively ($P = .98$). Mean body mass index (BMI) in mLDN and sLDN was 26.1 (19.1-29.2) and 24.7 (20.4-27.9), respectively ($P = .703$).

Operative time was divided into three parts (minute): 1) total time of surgery: (104 ± 21 vs. 114 ± 24; $P = .327$); 2) from induction of anesthesia to preparation of renal pedicle for clipping including renal artery and renal vein: (83 ± 24 vs. 89 ± 23; $P = .406$); 3) ischemic time (from ligation of renal artery to kidney immersion in ice slush) (4.03 vs. 4.07; $P = .592$). Surgical blood

Figure 3. Scar appearance of trocars in minilaparoscopic donor nephrectomy after three months.

loss was negligible in both groups. Mean hospital stay was similar between the two groups [2.1 (2-5) vs. 2.4 (2-5) days: $P = .346$]. Mean follow up time of recipient was 9 months (6-19 months). Kidney graft function; assessed by serum creatinine values (mg/dL) of recipients one month after transplantation and then every three months, was equivalent in both groups (1.58 vs. 1.86; $P = .206$). Two grafts were lost in recipients of sLDN donors, while only one was lost from mLDN donors. Rejection was the main reason of graft loss in all three aforementioned cases. There were no fatalities resulting from either procedure in donors. There were no cases of conversion to open surgery, vascular injury or graft extraction complication in both groups. No major peri- or post-operative complications occurred in both groups. Two patients in sLDN group and three patients in mLDN group had complication with Clavien Dindo grading type II (fever greater than 38.5°C longer than 48 hours that were managed by antibiotic therapy) ($P = .527$) (**Table 2**). PASQ is a validated questionnaire for the measurement of scar outcome and consists of five subscales. Mean appearance score and consciousness score a showed significantly better results in the mLDN group (**Table 3**) (**Figure 3**).

DISCUSSION

The only definitive therapy for end stage renal disease (ESRD) is renal transplantation. Even in developing countries, the availability of cadaveric organ is reaching a plateau while the burden of renal failure is escalating. Even after expanding criteria for cadaveric renal donors, the supply of kidneys is outpaced by the growing demand, so; modern techniques of kidney delivery should consider the cosmetic effect of live donor nephrectomy, in order to increase the willingness and concerns of potential donors.

Various techniques have been described for graft retrieval. Laparoscopic donor nephrectomy results in faster recovery, less hospital stay, better cosmetic results, and better quality of life of the donor and equal safety and graft function for recipients compared with open donor nephrectomy. Laparoscopic retrieval has become the gold standard over the last decade for harvesting the kidney from a living donors.[11,12] The hand-assisted laparoscopic donor nephrectomy (HALDN) for left side and hybrid technique using Satinsky clamp HALDN for right-sided has been used as a minimally invasive technique for organ donation.[13] LESS (laparoendoscopic single-site surgery) has been introduced to minimize the morbidity associated with laparoscopic surgery even more. It is hypothesized that reduced entry points will ultimately decrease morbidity, convalescence, and improve cosmetic outcome. Although there are increasing numbers of reports about the use of LESS all over the world, the potential benefit of LESS remains to be defined due to controversial data on postoperative pain control and its minimal effect on cosmesis.[14,15] LESS has some drawbacks that limit its routine use including the requirement of the flexible lens, clashing of instruments, and requirement of a steep learning curve and likewise, it seems that LESS is not an ergonomic approach for live donor nephrectomy.[16] Tisdale and colleagues[17] compared the operative and perioperative parameters after laparoscopic nephrectomy with intact specimen extraction through a Pfannenstiel or expanded port site incision. They reported reduced morbidity with intact specimen extraction through a Pfannenstiel incision such as shorter hospital stay, less analgesic requirement and reduced number of incisional hernia. LESS has also been associated with increased risk of complication, increased surgical cost, takes longer operative times, and carries a higher chance of conversion. Autorino and colleagues[18] in a systematic review and meta-analysis compared the LESS living-donor nephrectomy (LLDN) vs. standard laparoscopic donor nephrectomy. They reported similar visual analogue pain score, hospital stay, warm ischemia time and renal function of the recipient in two groups. The estimated blood loss and analgesic requirement were lower for LESS groups but LESS was more technically challeng-

Table 2. Demographic data of 100 cases randomly assigned to two groups.

Variables	Minilaparoscopic Donor Nephrectomy	Standard LaparoscopicDonor Nephrectomy	*P* Value
Mean age (years)	27.4 (20-38)	28.2 (21-43)	.98
Body mass index	26.1 (19.1-29.2)	24.7 (20.4-27.9)	.703
Total operative time (min)	104 ± 21	114 ± 24	.327
Warm ischemic time (min)	4.03	4.07	.592
Hospital stay (day)	2.1 (2-5)	2.4 (2-5)	.346
Complication (Clavien grade)	3 grade II	2 grade II	.527
Graft loss in recipient (No.)	1	2	.32
Serum creatinine in recipient (mg/dL)	1.58	1.86	.206

Table 3. Detailed information about subscales of PSAQD in mLDN and sLDN group.

Variables	mLDN	sLDN	*P* Value
Appearance (mean score)	34	29	.001
Consciousness (mean score)	22	18	.03
Symptom (mean score)	25	24	.741
Satisfaction with appearance (mean score)	31	28	.07
Satisfaction with symptoms (mean score)	18	18	.42

Abbreviations: mLDN, minilaparoscopic donor nephrectomy; sLDN, standard laparoscopic live donor nephrectomy.

ing than LLDN, as shown by a greater likelihood of conversion and longer operative time.

NOTES offers a potential of surgical intervention with the elimination of abdominal wall incisions. Vaginal extraction of the specimen following laparoscopic nephrectomy has been described a decade ago.[19] Currently, NOTES still represents an experimental surgical technique. There are few studies regarding using NOTES for laparoscopic nephrectomy in living donors.[6,20] NOTES in living donor nephrectomy and transvaginal kidney extraction is only applicable in selected female donors and this is a major drawback while at least fifty percent of donors are male. It also requires randomized controlled studies to further elucidate the potentials of this technique.

The development of miniaturized instruments has created a new dimension to conventional laparoscopy. Minilaparoscopy has been shown to be safe in almost all urologic indication and has been proposed for reduced postoperative pain and improved cosmetic results.[21] Minilaparoscopy has been applied broadly in general surgery studies under separate names, such as miniport, needlescopy, and microlaparoscopy. Li and colleagues[22] in a network meta-analysis of 43 randomized controlled trials, compared different kinds of laparoscopic cholecystectomy (single port, two ports, three ports, and four ports laparoscopic cholecystectomy and four ports minilaparoscopic cholecystectomy). They concluded that the best technique might be minilaparoscopy because of the highest level of cosmetic score, least postoperative complications, and minimal blood loss during operation. Graft outcome (either short term or long term) is one of the major concerns in donor nephrectomy. Minilaparoscopic donor nephrectomy applies the quite same principles of sLDN and no additional step is required, so not surprisingly, its effect on graft outcome is similar. No significant differences were seen between the two groups regarding operative time, postoperative complication, conversion to open surgery, hospital stay and graft survival. Like sLDN, donor's body mass index was not a limiting factor for mLDN.

There are some validated questionnaires such as cosmesis and body image score (CBIS),[23] PSAQ and etc. PASQ is a validated questionnaire for the measurement of scar outcome and consists of five subscales that were presented for plastic and reconstructive surgery in 2009.[10] Thus, we used this validated questionnaire for cosmetic appearance evaluation. Assessment of PSAQ data revealed significantly better cosmetic results in mLDN. Likewise, mLDN has other benefits: mLDN is quite similar to the standard technique and requires no specific additional training course for laparoscopic surgeons. Using the suprapubic trocar for vascular clipping in mLDN takes advantage of vascular clipping in a nearly perpendicular direction and as a result, it provided longer artery and vein for anastomosis. In contrast to LESS, no special and expensive instruments are needed for mLDN and we did not use disposable instruments (ports, Endo-GIA, ENDOCATCH bag). These modifications have positive impact on financial burden.

We accept that cosmetic and satisfaction assessment has some limitations. The cosmetic satisfaction of patients are dependent for many confounding factors such as age, sex, education, BMI, previous surgeries, believes, culture, and etc. that may be affect the final results. Likewise, psychosocial status of participants, thoughts and behaviors, physical functioning, physical and emotional impediments to role functioning, vitality and social functioning were not assessed and matched preoperatively. Cost-effectiveness is an important item that was not assessed and it is other drawback of our study.

CONCLUSIONS

Our experience in this randomized trial study revealed that peri- and post-operative findings were nearly similar between standard and minilaparoscopic live donor nephrectomy but minilaparoscopic has significant better cosmetic appearance than standard laparoscopic approach.

CONFLICT OF INTEREST

None declared.

REFERENCES

1. Ratner LE, Ciseck LJ, Moore RG, Cigarroa FG, Kaufman HS, Kavoussi LR. Laparoscopic live donor nephrectomy. Transplantation. 1995;60:1047-9.
2. Duchene DA1, Winfield HN. Laparoscopic donor nephrectomy. Urol Clin North Am. 2008;35:415-24.
3. Lucas SM1, Liaw A, Mhapsekar R, et al. Comparison of donor, and early and late recipient outcomes following hand assisted and laparoscopic donor nephrectomy. J Urol. 2013;189:618-22.
4. Simforoosh N1, Basiri A, Tabibi A, Shakhssalim N, Hosseini Moghaddam SM. Comparison of laparoscopic and open donor

nephrectomy: a randomized controlled trial. BJU Int. 2005;95:851-5.

5. Lewandowski PM1, Leslie S, Gill I, Desai MM. Laparo-endoscopic single-site donor nephrectomy: techniques and outcomes. Arch Esp Urol. 2012;65:318-28.
6. Allaf ME, Singer A, Shen W, et al. Laparoscopic live donor nephrectomy with vaginal extraction: Initial report. Am J Transplant. 2010;10:1473-7.
7. Simforoosh N, Soltani MH, Hosseini Sharifi SH, et al. Minilaparoscopic live donor nephrectomy: initial series. Urol J. 2014;10:1054-8.
8. Simforoosh N, Sarhangnejad R, Basiri A, et L. Vascular clips are safe and a great cost-effective technique for arterial and venous control in laparoscopic nephrectomy: single-center experience with 1834 laparoscopic nephrectomies. J Endourol. 2012;26:1009-12.
9. Simforoosh N, Soltani MH, Basiri A, et al. Evolution of laparoscopic live donor nephrectomy: a single-center experience with 1510 cases over 14 years. J Endourol. 2014;28:34-9.
10. Durani P, McGrouther DA, Ferguson MW. The Patient Scar Assessment Questionnaire: a reliable and valid patient-reported outcomes measure for linear scars. Plast Reconstr Surg. 2009;123:1481-9.
11. Ratner LE, Montgomery RA, Maley WR, et al. Laparoscopic live donor nephrectomy: the recipient. Transplantation. 2000;69:2319-23.
12. Kok NF, Lind MY, Hansson BM, et al. Comparison of laparoscopic and mini incision open donor nephrectomy: single blind, randomised controlled clinical trial. BMJ. 2006;333:221.
13. Kim BS, Kim KH, Yoo ES, Kwon TG. Hybrid technique using a Satinsky clamp for right-sided transperitoneal hand-assisted laparoscopic donor nephrectomy: comparison with left-sided standard hand-assisted laparoscopic technique. Urology. 2014;84:1529-34.
14. Kaouk JH, Autorino R, Kim FJ, et al. Laparoendoscopic single-site surgery in urology: worldwide multi-institutional analysis of 1076 cases. Eur Urol. 2011;60:998-1005.
15. Pini G1, Rassweiler J. Minilaparoscopy and laparoendoscopic single-site surgery: mini- and single-scar in urology. Minim Invasive Ther Allied Technol. 2012;21:8-25.
16. Oh TH. Current status of laparoendoscopic single-site surgery in urologic surgery. Korean J Urol. 2012;53:443-50.
17. Tisdale BE1, Kapoor A, Hussain A, Piercey K, Whelan JP. Intact specimen extraction in laparoscopic nephrectomy procedures: Pfannenstiel versus expanded port site incisions. Urology. 2007;69:241-4.
18. Autorino R, Brandao LF, Sankari B, et al. Laparoendoscopic single-site (LESS) vs laparoscopic living-donor nephrectomy: a systematic review and meta-analysis. BJU Int. 2015;115:206-15.
19. Gill IS, Cherullo EE, Meraney AM, Borsuk F, Murphy DP, Falcone T. Vaginal extraction of the intact specimen following laparoscopic radical nephrectomy. J Urol. 2002;167:238-41.
20. Alcaraz A1, Musquera M, Peri L, et al. Feasibility of transvaginal natural orifice transluminal endoscopic surgery-assisted living donor nephrectomy: is kidney vaginal delivery the approach of the future? Eur Urol. 2011;59:1019-25.
21. Pini G, Porpiglia F, Micali S, Rassweiler J. Minilaparoscopy, needlescopy and microlaparoscopy: decreasing invasiveness, maintaining the standard laparoscopic approach. Arch Esp Urol. 2012;65:366-83.
22. Li L, Tian J, Tian H, Sun R, Wang Q, Yang K. The efficacy and safety of different kinds of laparoscopic cholecystectomy: a network meta analysis of 43 randomized controlled trials. PLoS One. 2014;9:e90313.
23. Lind MY, Hop WC, Weimar W, JN IJ. Body image after laparoscopic or open donor nephrectomy. Surg Endosc. 2004;18:1276-9.