ORIGINAL ARTICLE

Stenting the ureteroneocystostomy reduces urological complications in kidney transplantation: a noninferiority randomized controlled trial, SPLINT trial

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The trial was registered at the (Dutch) Netherlands Trial Registry: Trial NL4358 (NTR4498).

SUMMARY

The role of ureteral stents in living-donor kidney transplantation remains uncertain. In this randomized controlled trial (SPLINT), we compared urological complications in living-donor kidney transplantations performed with or without stents. We included 200 consecutive patients that received living-donor kidney transplantations at the Erasmus MC, University Medical Center, Rotterdam. Patients (124 males, 76 females, mean age 54 ± 13) were randomized for suprapubic externalized single J stents ($N = 100$) or no stent ($N = 100$). The primary outcome was the probability of a percutaneous nephrostomy insertion (PCN) during a 12-month follow-up. To assess whether no stenting is noninferior to stenting, we allowed the probability of a PCN to increase by at most 5% (this is the noninferiority margin). Baseline characteristics were comparable between groups. In the no-stent group, there were more PCN insertions, 14% (95% CI 4.3–23.7%); urinary leakages, 12% (95% CI 5.4–21.3%); and surgical re-interventions because of urological complications, 8% (95% CI 1.5–14.5%). The stent group had more hematuria, 26% (95% CI 13.1–38.9%); and graft rejections, 15% (95% CI 2.7–27.3%). Patients in both groups had similar mean GFRs at several time points. Besides a better Euro-Qol-5D in the no-stent group at 2 and 6 weeks postoperative, similar quality of life was reported based on SF-36 and Euro-Qol-5D scores. In this trial, noninferiority has not been demonstrated for no-stent placement in relation to the number urological complications.

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Introduction

Kidney transplantation is the optimal treatment offering long-term benefits to the majority of patients with chronic kidney failure. However, urological complications after kidney transplantation, such as urinary leakage and ureteral strictures, are associated with significant morbidity, surgical and radiological

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interventions, prolonged hospital stays, and even mortality. Most urological complications are related to the ureteroneocystostomy, and they are treated with a percutaneous nephrostomy (PCN) [1,2].

The role of ureteral stents in living-donor kidney transplantations remains uncertain. A Cochrane review, published in October 2005 and revised in 2013, suggests that routine prophylactic stenting reduces the incidence of major urological complications. However, there are some limitations to this Cochrane review. First of all, most included studies are from 1995 to 2000. As in the last 20 years many improvements have been made in the immunosuppressive treatment, we wonder how representative these data are for current medicine. Secondarily, different kinds of stents (lengths and caliber) have been used and none of them include an externalized stent. Furthermore, the study designs of the seven included articles were heterogeneous with different types of donors, intervention periods, outcome assessments, and statistical analysis [3,4]. Stent placement also has some disadvantages. The complications associated with stents include infections, obstructions, stent migrations, breakage, stone formation, hematuria, and secondary ureteral obstructions [4–9].

In this trial (Stent PLacement IN living-donor kidney Transplantation, SPLINT), we tested the hypothesis that omitting a ureteral stent in kidney transplantation might be as effective as stenting, and it might even reduce the number of urological complications, because of the absence of stent-related problems. We also followed patients for 1 year to evaluate quality of life (QOL).

Methods

Study design

In this randomized controlled trial, we included all patients that received a living-donor kidney transplantation at the Erasmus MC, University Medical Center, Rotterdam, the Netherlands, between April 2014 and March 2017. Exclusion criteria were as follows: declined informed consent, age <18 years, a reconstructed urinary tract or conduit after total or partial cystectomy, bladder dysfunction that required continuous or intermittent catheterization, and a donor kidney with duplicated ureters. Patients with primary focal segmental glomerulosclerosis (FSGS) that still had residual urinary output were also excluded. FSGS is known to recur rapidly in kidney grafts, in which case the first sign is proteinuria. An externalized stent allows one to distinguish whether proteinuria originated in the transplanted kidney or the native kidneys. Furthermore, we excluded recipients that were included in another ongoing clinical trial.

We randomized 200 patients to either stent placement ($N = 100$, Teleflex®, suprapubic externalized single J stent, 7 fr) or no-stent placement ($N = 100$). In our center, the external stent has been standard care for several years. Randomization was performed with a concealed opaque envelope system prepared by an independent statistician at the Erasmus MC, University Medical Center, Rotterdam. Patients were randomized after intubation in the operating room. As a result of the use of an externalized stent, blinding was not possible. There were no blocks and no stratification methods used during randomization.

The Medical Ethics Committee of the Erasmus MC, University Medical Center, Rotterdam, approved the trial protocol (MEC-2013-196), and the study was registered at the (Dutch) Netherlands Trial Registry: Trial NL4358 (NTR4498).

Surgical technique

The donor nephrectomy was performed with either a fully laparoscopic, a robot-assisted, or hand-assisted retroperitoneoscopic approach. The kidney recipients underwent transplantation with an extraperitoneal approach to the iliac fossa. Firstly, the renal vein was anastomosed to the external iliac vein, followed by the renal artery that was anastomosed to the external iliac artery. Then, an extravesical ureteroneocystostomy was performed, as described by Lich-Gregoir [10,11]. The detrusor muscle was closed over the anastomosis with one or two interrupted absorbable sutures to create a submucosal tunnel, with an antireflux mechanism. The stent group received a 7-fr suprapubic externalized single J stent (Teleflex®), and it was removed 9 days postoperatively. A transurethral urinary bladder catheter was placed according to standard care in all patients; this catheter was removed after 7 days. All patient had a nuclear renogram scan and an ultrasound one day after surgery. Furthermore, daily serum creatinine levels were determined during hospital stay.

Power calculation

The SPLINT trial was designed as a noninferiority study. It was powered to demonstrate that omitting a stent would not lead to a relevant increase in the

urological complication rate, that is, the percentage of required PCN drainages. To show that the increase in patients without a stent requiring a PCN is at most 5% (noninferiority margin), 96 patients per arm were required (one-side alpha = 0.025, power = 90%). This calculation was based on the assumption that among patients that received stents, 20% would require a PCN [1], and among patients that received no stent, 9% would require a PCN [2]. To allow room for a few nonevaluable cases, we randomized 100 patients per arm.

Definitions

Baseline data of the recipients included gender, age, American Society of Anesthesiologists (ASA) classification, number of previous transplantations, body mass index (BMI), warm and cold ischemia times, and preemptive transplantations (prior to starting dialysis). Our primary outcome was a PCN insertion within 12 months. Indications for a PCN insertion were as follows: urinary leakage (detected with a nuclear renogram scan or demonstrated by high creatinine levels in the fluid excretion from the wound or from the drain) or a rise in serum creatinine combined with hydronephrosis (detected with ultrasound). Our secondary outcome was graft function, based on the glomerular filtration rate (GFR), duration of surgery, perioperative blood loss, any surgical re-intervention performed within <12 months of kidney transplantation (including nonurological re-interventions), length of hospital stay, hematuria (defined as macroscopic hematuria during hospital admission), urinary tract infection (UTI), and graft rejection <1 month after kidney transplantation. UTI was scored in case of a urinary culture with a bacterial load of $\geq 10^5$ CFU/ml that was treated with antibiotics. Rejection was scored if patients received antirejection treatment (methylprednisolone intravenous, IVIG, alemtuzumab, r-ATG). History of smoking included current or past smokers.

Quality of life questionnaires

We evaluated QOL, health state, work effort, and disabilities in daily life with two validated questionnaires: the Euro-Qol-5D and the Short Form survey 36 (SF-36) [12,13]. All questionnaires were completed preoperatively and at different time points postoperatively (at 2 and 6 weeks and at 3, 6, 9, and 12 months). Repeated QOL measurements were compared with a mixed-effects model for repeated measurements.

Immunosuppressive treatment

Immunosuppressive treatments included intravenous basiliximab as induction therapy, given on the day of surgery and on day 4 post-transplantation. Postoperative immunosuppression also included tacrolimus, mycophenolate mofetil, and prednisone. The prednisone was tapered off over time and discontinued at 4 months after transplantation.

Statistical analysis

All analyses were performed with IBM SPSS Statistics for Windows (version 21.0. Armonk, NY, USA: IBM Corp) *and R 3.5* [R Core Team (2012); a language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. ISBN 3-900051-07-0, URL http://www.R-project.org/]. We performed an intention-to-treat analysis. Therefore, patients were analyzed in the group in which they were originally allocated. For the primary parameter, we calculated beta with a 95% confidence interval (95% CI) using a generalized linear model for the risk difference for binominal variable and univariate analysis of variance for continuous variable. As the number of urinary leakage was 0, we were not able to use the generalized linear model, here, we calculated an exact confidence interval for a risk difference [14].

For secondary parameters: Continuous variables with a distribution that is approximately normal are presented as the mean and standard deviation, and comparisons were evaluated with the independent *t*-test. Variables with skewed distributions are presented as the median (range), and comparisons were evaluated with the Mann–Whitney *U*-test. Categorical variables are presented as numbers with percentages, and comparisons were evaluated with the chi-square test.

Results

Baseline characteristics

Between April 2014 and March 2017, 200 patients were included in the SPLINT trial. Because of perioperative difficulties, one patient received a stent, although he was allocated to the no-stent group. As this is an intention-to-treat analyses, this patient was analyzed in the no-stent group. The cohort comprised 124 males and 76 females with a mean age of 54 $\pm$ 13 years. Baseline characteristics were comparable for both groups (Table 1).

Table 1. Baseline characteristics

Characteristic	Total (*N* = 200)	No stent (*N* = 100)	Stent (*N* = 100)	*P*-value
Recipient, gender *N* (%)				
M	124 (62)	63 (63)	61 (61)	0.771
F	76 (38)	37 (37)	39 (39)	
Recipient age, years; mean ± SD	54 ± 13	55 ± 13	52 ± 14	0.170
Donor gender, *N* (%)				
M	81 (41)	45 (45)	36 (36)	0.195
F	119 (59)	55 (55)	64 (64)	
Donor age, years; mean ± SD	54 ± 12	54 ± 12	53 ± 13	0.572
ASA, *N* (%)				
2	28 (14)	12 (12)	16 (16)	0.524
3	164 (82)	85 (85)	79 (79)	
4	8 (4)	3 (3)	5 (5)	
Number of KTs, *N* (%)				
1	173 (86)	90 (90)	83 (83)	0.239
2	19 (10)	6 (6)	13 (13)	
3	8 (4)	4 (4)	4 (4)	
Laparoscopic technique, *N* (%)	123 (62)	61 (61)	62 (62)	0.884
Recipient BMI, mean ± SD	27 ± 5	28 ± 5	27 ± 5	0.408
History of smoking, *N* (%)	123 (61)	59 (59)	64 (64)	0.467
Pre-emptive KT, *N* (%)	102 (51)	48 (48)	54 (54)	0.396
Residual urinary production, *N* (%)	172 (86)	83 (83)	89 (89)	0.221
Ureteral length, cm; mean ± SD	9 ± 2	9 ± 2	9 ± 2	0.367
First warm ischemia time, min; mean ± SD	3 ± 1	3 ± 1	3 ± 2	0.196
Cold ischemia time, min; mean ± SD	140 ± 29	142 ± 31	139 ± 27	0.494
Second warm ischemia time, min; mean ± SD	20 ± 7	20 ± 7	20 ± 8	0.876

ASA, American Society of Anesthesiologists; BMI, body mass index; F, female; KT, kidney transplantation; M, male; *N*, number; SD, standard deviation.

Urological complications

In the no-stent group, 22 patients (22%) received a PCN after transplantation (Table 2). Of this group, 11 patients received a PCN because of urinary leakage. Five urinary leakages were resolved without further interventions; four patients required a surgical re-intervention to treat the urinary leakage; and two patients underwent both an antegrade balloon dilatation and a surgical re-intervention. One patient in the no-stent group with urinary leakage did not receive a PCN, but underwent immediate surgical repair. In the no-stent group, another 11 patients received a PCN because of hydronephrosis. Of these patients, eight did not require an additional intervention, one patient underwent a balloon dilatation, and two patients received both a balloon dilatation and a surgical re-intervention. One patient in the no-stent group with hydronephrosis because of a blood clot in the ureter did not receive a PCN, but underwent surgical repair directly.

In the stent group, eight patients (8%) received a PCN after transplantation, all because of hydronephrosis. One patient underwent balloon dilatation, and two patients underwent a balloon dilatation, followed by a surgical re-intervention.

To assess whether no stenting is noninferior to stenting, we allowed an increase of at most 5% in the number of patients without stent requiring a PCN (i.e., a noninferiority margin of 5%). There were more PCN insertions in the no-stent group, 14% (95% CI 4.3–23.7%). Moreover, compared to the stent group, the no-stent group had more urinary leakages, 12% (95% CI 5.4–21.3%); and surgical re-interventions because of urological complications, 8% (95% CI 1.5–14.5%). As the CI extends below the noninferiority margin, noninferiority of no-stent placement had not been demonstrated. The number of PCNs placed because of hydronephrosis was similar between groups. Details are shown in Fig. 1 and Table 2.

Overall outcome

There were no significant differences between the stent and no-stent group regarding the duration of surgery,

Table 2. Urological complications within 12 months

Characteristics	Total (*N* = 200)	No stent (*N* = 100)	Stent (*N* = 100)	Risk difference (%)	95% CI
PCN insertion, *N* (%)	30 (15)	22 (22)	8 (8)	14	4.3 to 23.7
Urinary leakage, *N* (%)	12 (6)	12 (12)	0 (0)	12	5.4 to 21.3
Hydronephrosis, *N* (%)	20 (10)	12 (12)	8 (8)	4	−4.3 to 12.3
Surgical re-intervention because of urological complications, *N* (%)	12 (6)	10 (10)	2 (2)	8	1.5 to 14.5
Antegrade balloon dilatation, *N* (%)	8 (4)	5 (5)	3 (3)	2	−3.4 to 7.4

CI, confidence interval; *N*, number; PCN, percutaneous nephrostomy insertion.

blood loss, total number of surgical re-interventions within 12 months (including nonurological re-interventions), UTIs, urosepsis, deaths, wound infections, and readmissions within 1 and 12 months after transplantation. In the stent group, there were more patients with macroscopic hematuria than in the no-stent group, 26% (95% CI 13.1–38.9%). In addition, compared to the no-stent group, more patients in the stent group required treatment because of graft rejection within 1 month after transplantation, 15% (95% CI 2.7–27.3%) (Table 3). Stented patients had a longer hospital stay because of our internal protocol (discharge only after stent removal) (mean: 13 ± 6 vs. 10 ± 4 days). In the no-stent group, one patient died of non-Hodgkin lymphoma. In the stent group, two patient died: one because of respiratory insufficiency caused by Guillain–Barre syndrome and the other patient because of cardiac reasons.

Graft outcome

We did not detect any differences between both groups regarding the mean GFR on days 7 or 14 or at 1, 3, 6, or 12 months after transplantation (Table 4).

Quality of life questionnaires

We compared QOL outcomes correcting for baseline at the various time points using a linear mixed model. Besides a better Euro-Qol-5D in the no-stent group 2 and 6 weeks postoperative, we could not demonstrate an effect of the stent ($P = 0.56$ for the multivariable test for the SF-36 and $P = 0.06$ for the multivariable test for the Euro-Qol-5D) (Tables 5 and 6).

Discussion

This randomized controlled trial in living-donor kidney transplantation investigated the influence of stent versus no-stent placement. We found more PCN insertions, urinary leakages, and surgical re-interventions because of urological complications in the no-stent group. In the stent group, there were more hematuria and graft rejection. In general, we could not demonstrate an effect of the stent on quality of life, besides a better Euro-Qol-5D result in the no-stent group 2 and 6 weeks postoperative.

This trial was conducted to provide well-defined, evidence-based arguments for ureteric stent placement in kidney transplantation. Previously, five randomized controlled trials [15–19] were conducted on stent placement, but they differed in the use of living-donor or deceased-donor kidneys, intravesical or extravesical anastomoses, and the type of stent used. According to those studies, stenting seemed to be favored, but it remained uncertain whether stenting should be considered routine or only performed when strictly defined criteria were met. A Cochrane review on this topic supported the use of ureteral stents, but they did not state recommendations for duration and the type of stent [4]. Timing of stent removal remains difficult. A recently published meta-analysis supports stent removal within three weeks postoperatively; however, this statement was based on double J stents [20].

Previously, we investigated whether the type of anastomosis (extravesical vs. intravesical; INEX trial) was a risk factor for PCN insertion [21]. Both groups received a ureteral stent, although a different stent than which was used in the current SPLINT trial. We found no difference in the number of PCN insertions between groups that received intravesical or extravesical anastomoses (20% vs. 20%). However, the number of UTIs was lower in the extravesical group. Currently, our standard of care includes the extravesical anastomosis.

Based on the results of the current study, we are convinced that ureteric stent placement with an extravesical ureteroneocystostomy could reduce the number of urological complications in kidney transplantation. Only

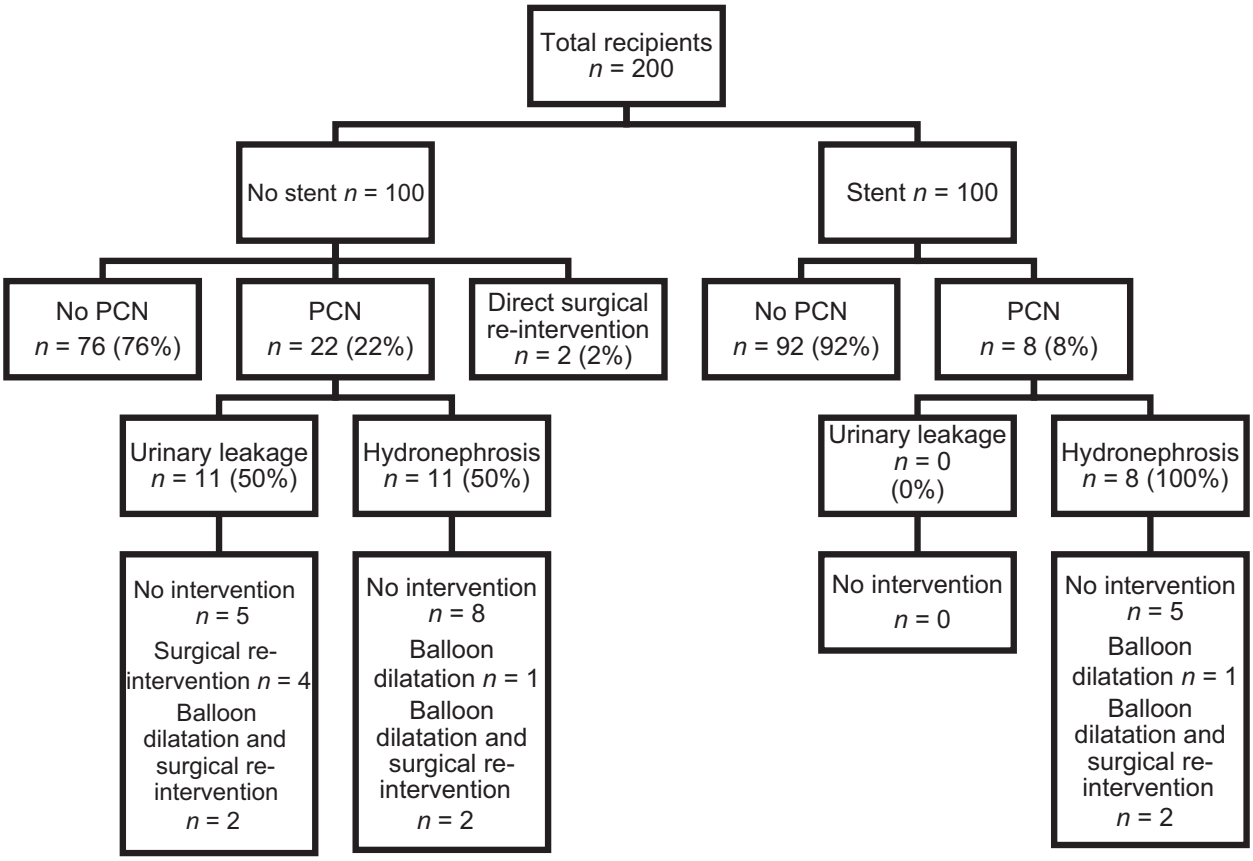

Figure 1 Flowchart SPLINT trial. N, number; PCN, percutaneous nephrostomy.

Table 3. Overall outcome

Outcome	Total (*N* = 200)	No stent (*N* = 100)	Stent (*N* = 100)	*P*-value
Duration of surgery, min; mean ± SD	116 ± 36	114 ± 39	119 ± 34	0.314
Blood loss, ml; median (range)	150 (0–2000)	150 (0–2000)	150 (0–1300)	0.451
Any surgical re-intervention in <12 months, *N* (%)	34 (17)	21 (21)	13 (13)	0.132
Hematuria in <1 month, *N* (%)	126 (63)	50 (50)	76 (76)	**<0.001**
UTI in <1 month, *N* (%)	47 (24)	27 (27)	20 (20)	0.243
Urosepsis in <1 month, *N* (%)	9 (5)	5 (5)	4 (4)	0.733
Wound infection in <1 month, *N* (%)	22 (11)	14 (14)	8 (8)	0.175
Rejection in <1 month, *N* (%)	57 (29)	21 (21)	36 (36)	**0.019**
Biopsy-proven rejection in <1 month, *N* (%)	40 (20)	11 (11)	29 (29)	**0.001**
Total length of hospital stay, days; mean ± SD	11 ± 5	10 ± 4	13 ± 6	**<0.001**
Readmission in <1 month, *N* (%)	47 (24)	27 (27)	20 (20)	0.243
Readmission in <12 months, *N* (%)	110 (55)	57 (57)	53 (53)	0.570
Number of readmissions per person in <12 months; median (range)	1 (0–17)	1 (0–12)	1 (0–17)	0.563
Death <12 months, *N* (%)	3 (1.5)	1 (1)	2 (2)	0.561

N, number; SD, standard deviation; UTI, urinary tract infection.

Bold values are statistically significant.

8% of patients received PCN insertions in the stented extravesical anastomosis group. This proportion was considerably lower than the 20% in the above-mentioned INEX trial [21].

Although stent placement increased the duration of ureteral anastomosis, it did not influence the total duration of surgery. However, the mean total hospital stay was longer in the stent group than in the no-stent

Table 4. Graft outcome

Renal function after KT mean ± SD	No stent (*N* = 100) GFR ml/min	Stent (*N* = 100) GFR ml/min	*P*-value
7 days	41 ± 15	41 ± 19	0.950
14 days	46 ± 15	46 ± 17	0.778
1 month	48 ± 15	47 ± 16	0.794
3 months	49 ± 15	48 ± 16	0.576
6 months	51 ± 16	49 ± 16	0.324
12 months	52 ± 18	52 ± 18	0.922

GFR, glomerular filtration rate; KT, kidney transplantation; SD, standard deviation.

group. This is due to the fact that in our hospital, stented patients were only discharged after stent removal.

Remarkably, we found a higher number of rejections in the stent group than in the no-stent group. These patients had received antirejection treatments (intravenous methylprednisolone, IVIG, alemtuzumab, or r-ATG) within 1 month after transplantation. We could not find any explanation for this finding. We speculate that, because patients with stents had prolonged hospital stays, rise of serum creatinine might have been detected more rapidly, because of frequent in-hospital evaluations, compared with outpatient visits. In addition, urine production can be monitored more accurately in patients with externalized stents than in patients without a stent; this monitoring might have led to a relatively low threshold for biopsy. However, we cannot completely disclaim that the stent (being a foreign body) could facilitate an immune response leading to rejection. Note that there is no literature, which does substantiate this.

This study had a few limitations. Most importantly, the suprapubic externalized type of stent (single J stent) used in this trial is not a stent commonly used. Most transplant centers use the double J stent, and literature indicated that the double J stent is also associated with minor urological complications. Furthermore, we have a relatively high number of PCN insertions compared to literature. In our clinic, we have a low threshold to place a PCN, as this is considered a minimally invasive event. Even a mild hydronephrosis leads to PCN insertion, either for therapeutically benefit or as diagnostic tool before performing an biopsy. As in this trial the data are collected prospectively, the database is more complete and accurate, possibly resulting in a higher percentage of complications than the complication rates that are mentioned in other kinds of publications. Our

Table 5. SF-36 questionnaire

Time point	No stent Mean	95%CI Lower limit	95%CI Upper limit	Stent Mean	95%CI Lower limit	95%CI Upper limit	Delta Mean	*P*-value
2 weeks	21.2	13.3	29.2	18.1	10.3	26.0	−3.1	0.272
6 weeks	30.3	22.3	38.3	26.9	18.9	34.9	−3.5	0.241
3 months	32.9	24.7	41.1	35.7	27.6	43.8	2.8	0.381
6 months	35.8	27.7	44.0	34.7	26.6	42.8	−1.1	0.720
9 months	40.2	31.9	48.5	38.7	30.5	47.0	−1.4	0.666
12 months	40.8	32.6	49.0	39.3	31.2	47.4	−1.5	0.639
Preoperative scores	59.4	55.3	63.4	57.9	53.9	62.0	−1.5	

Table 6. Euro-Qol-5D questionnaire

Postoperative time point	No stent Mean	95% CI Lower limit	95% CI Upper limit	Stent Mean	95% CI Lower limit	95% CI Upper limit	Delta Mean	*P*-value
2 week	−0.17	−0.22	−0.12	−0.24	−0.30	−0.19	−0.07	**0.030**
6 weeks	−0.07	−0.12	−0.02	−0.14	−0.20	−0.09	−0.07	**0.037**
3 months	−0.07	−0.12	−0.02	−0.07	−0.13	−0.02	0.00	0.917
6 months	−0.06	−0.11	−0.01	−0.10	−0.15	−0.04	−0.04	0.230
9 months	−0.07	−0.12	−0.02	−0.05	−0.11	0.00	0.02	0.628
12 months	−0.08	−0.13	−0.03	−0.08	−0.14	−0.02	0.00	0.984
Preoperative scores	−0.17	−0.21	0.12	−0.21	−0.25	0.16	−0.04	

Bold values are statistically significant.

number of re-interventions because of urological complications is comparable to literature. Cost-effectiveness data were collected during this trial and will be published separately.

A previous retrospective study by Vogel *et al.* that included 76 patients compared 43 externalized stents and 33 double J stents. They reported that the incidences of leakage from the ureteroneocystostomy were 13.9% for externalized stents and 0% for double J stents. Furthermore, they found a 2-day reduction in hospital stay time with the internal stent [22]. Gomes *et al.* also retrospectively reviewed the use of externalized stents, internal stents, and no stent, in 2061 recipients of kidney transplants. In their cohort, the incidences of urological complications were 17.3% in the externalized stent group, 8.4% in the no-stent group, and 5.4% in the double J stent group ($P < 0.0005$) [23]. The authors concluded that externalized stents should be avoided, because they were associated with a high urological complication rate. Guleria *et al.* [24] also reduced urological complications by changing their technique from no stent (7.7%) to a double J stented (for a period of 6 weeks) ureteroneocystostomy (3.8%). Unfortunately, those studies had retrospective designs. Furthermore, patients with an external stent do not need an additional cystoscopy for stent removal. By lowering the number of interventions, external stents may reduce patients' morbidity and costs. Therefore, we recently started a new trial at the Erasmus MC, University Medical Center, Rotterdam, in which we investigate whether single J or double J stenting is superior in reducing the number of urological complications.

In this trial, noninferiority has not been demonstrated for no-stent placement in relation to the number of urological complications.

Authorship

L.S.S.O.: performed research, analyzed data and wrote the manuscript. R.C.M., F.J.M.F.D., H.J.A.N.K., T.C.K.T., H.H. and J.v.d.W.: performed research and wrote the manuscript. S.P.W.: analyzed data. J.N.M.I. and T.T.: designed research, performed research, analyzed data and wrote the manuscript.

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Conflict of interest

The authors have declared no conflicts of interest.

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