Safety and Effectiveness of Externalized Ureteral Catheter in Tubeless Percutaneous Nephrolithotomy

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ABSTRACT

Purpose: To review the safety and effectiveness of tubeless percutaneous nephrolithotomy (PCNL) with an externalized ureteral catheter (EUC) compared with standard PCNL with nephrostomy tube and tubeless PCNL with double-J (DJ) stent following uncomplicated PCNL and the absence of residual stones.

Materials and Methods: Patients with kidney stones who underwent uncomplicated PCNL between January 2000 to December 2017 and had no residual stones were retrospectively evaluated. The 766 patients were divided into standard PCNL with nephrostomy tube (group 1; 350 patients), tubeless PCNL with DJ stent (group 2; 189 patients), and tubeless PCNL with EUC (group 3; 227 patients). Demographic characteristics, stone-related factors, perioperative and postoperative parameters were analyzed.

Results: Demographic and stone-related characteristics were comparable. The differences in the mean operative time and complication rates were not significant. Postoperative hospitalization period was shorter in group 3 (3.19 ± 2.2 days) compared with group 1 (4.12 ± 2.4 days; $p < .001$) but not to that of group 2 (3.44 ± 2.8 days; $p = .680$). Postoperative pain score was lower in group 3 (3.24 ± 1.1) compared with both group 1 (6.36 ± 1.7; $p < .001$) and group 2 (4.85 ± 1.1; $p < .001$). Urine leakage complication was lower in group 3 (0.4%) compared with group 1 (2.9%, $p = .038$) but not to that of group 2 (0.5%; $p = .897$).

Conclusions: Tubeless PCNL is effective and safe for uncomplicated PCNL in the absence of residual stones. Tubeless PCNL with EUC is associated with decreased pain, hospitalization time, and urine leakage compared with standard PCNL. However, it is only associated with decreased pain when compared with tubeless PCNL with DJ stent.

Keywords: *double-j stent; externalized ureteral catheter; kidney stone; percutaneous nephrolithotomy; tubeless PCNL*

INTRODUCTION

Kidney stone is a common urological disorder that affects 10% of people; 70% of them experience the recurrence of kidney stone.[1] Percutaneous nephrolithotomy (PCNL) has increased the successful outcome and effectiveness of kidney stone treatment. PCNL is recognized as a management of choice for a complex and large kidney stone.[2,3] In standard practice, a nephrostomy tube is placed following PCNL to maintain urinary drainage, prevent urinary extravasation, tamponade the bleeding, and provide access for a second-look procedure if needed.[4,5] However, nephrostomy tube placement is associated with more postoperative discomfort, longer hospitalization, more analgesic requirement, and higher cost.[6,7] Therefore, a modification by applying a ureteral stent instead of a nephrostomy tube following PCNL, known as tubeless PCNL, was first introduced by Bellman *et al.*[8] Systematic reviews have demonstrated the effectiveness and safety of tubeless PCNL.[7,9] Although found to be superior compared with standard PCNL, ureteral stent placement also has several disadvantages such as dysuria, pollakiuria, and postoperative cystoscopy for stent removal.[1,5]

Since its introduction, tubeless PCNL has undergone various modifications to improve the outcome.[10] There have been several reports of the use of an externalized ureteral catheter (EUC) instead of a double-J (DJ) stent in tubeless PCNL.[10–13] Gonen *et al.* reported that EUC is as feasible and safe as DJ stent.[12] EUC could reduce stent-related discomfort and avoid cystoscopy for removal. However, Telha *et al.* showed that tubeless PCNL with a DJ stent was superior to EUC.[14] Although safe and feasible, the role of EUC in tubeless PCNL remains contentious. Direct comparisons between EUC and DJ stent in tubeless PCNL were also lacking in the current literatures. Therefore, this study was designed to review the safety and effectiveness of tubeless PCNL with an EUC compared with standard PCNL and tubeless PCNL with a DJ stent following uncomplicated PCNL in the absence of residual stones. The results from this study will guide urologists and patients to decide on the treatment modality and to select the optimal minimally-invasive surgical treatment technique.

MATERIALS AND METHODS

Study population

Between January 2000 and December 2017, from 1,200 patients that underwent the PCNL procedure at Dr. Cipto Mangunkusumo Hospital, 766 of them that fulfilled the inclusion criteria were enrolled in this study. The patients were classified into standard PCNL with nephrostomy tube (group 1), tubeless PCNL with DJ stent (group 2), and tubeless PCNL with EUC (group 3). The preoperative parameters and postoperative outcomes were recorded in the same way in all groups. Our institutional ethics committee has accepted this study protocol (0553/UN2.F1/ETIK/2018).

Inclusion and exclusion criteria

All participants with caliceal, pelvic, and upper ureteral stones regardless of stone burden, hydronephrosis severity, and renal function were included in the study. The inclusion criteria of this study were patients aged 18 years or older, no congenital abnormalities, single-tract access, minimum bleeding, and complete removal of kidney stone (residual stone <4 mm) as determined by intraoperative fluoroscopy. Patients with bilateral stones, significant

complication during the PCNL procedure, and different PCNL techniques (mini PCNL, micro PCNL, ultra mini PCNL) were excluded from this study.

Procedures

All PCNL procedures were accomplished by a team of endourologists with three different main operating surgeons (N.R., P.B., W.A.). All patients received preoperative prophylactic antibiotics. The PCNL procedure was performed under general or spinal anesthesia. Our PCNL technique was similar to the technique reported by Ko *et al.*[15] First, retrograde ureteral catheterization was performed when the patient was in the lithotomy position and then changed into the prone position. Percutaneous renal access was attained using an 18-gauge needle with C-armed fluoroscopy guidance. After needle position was confirmed, a guide wire was secured into the needle. Tract dilatation was completed using an Amplatz dilator, and an Amplatz sheath (26-30 Fr) was introduced into the collecting system. The stone was identified using a rigid nephoscopy and fragmented with either a pneumatic or ultrasonic lithotriptor. There was no significant differences between pneumatic and ultrasonic lithotripter in terms of success rate and complications.[16] Upon completion, the surgeon endoscopically and radiographically examined the patient for any residual fragments or perforation.

The patients were classified into three groups. An 8–10.5 Fr nephrostomy tube was secured into the kidney of the patients that underwent standard PCNL (group 1). Postoperatively, the nephrostomy tube was removed if there were no signs of leakage, pain, or fever. In patients that underwent tubeless PCNL with a DJ stent (group 2), a DJ stent was placed antegradely without placement of a nephrostomy tube. The ureteral DJ stent was withdrawn on an average of two weeks after surgery. In patients that underwent tubeless PCNL with an EUC (group 3), neither a DJ stent nor a nephrostomy tube was placed after the procedure. In group 3, the EUC was used for internal drainage and taken out on an average of two days postoperatively.

Evaluations

Data from clinical history and examination, complete blood count, serum creatinine, urea level and radiological investigations (intravenous pyelography or non-contrast computed tomography scans) were recorded for each participating patient. Demographic details, stone characteristic, operation time, perioperative parameters, laboratory parameters, hospitalization period, postoperative pain, and postoperative complications were compared between the three groups. Postoperative pain was assessed uniformly on postoperative day (POD) 1 using the visual analog scale (VAS). Pain score was ranged from 0 (no pain) until 10 (maximum intolerable pain). Hospitalization period was measured from the surgery until discharge with discharge criteria: minimal or no pain, minimal or no flank leakage, no urinary retention, minimal or no hematuria, and stable vital signs.

Statistical Analysis

Analysis of the collected data was performed using Statistical Package for the Social Sciences (SPSS) software version 25. Normality of the data was analyzed by using the Kolmogorov–Smirnov test. The data are expressed as the mean (SD) and number (percentage) based on the type of data. The outcomes of the three groups were compared using the one-way

ANOVA test for the continuous variables with normal distributions and Kruskal-Wallis test for non-normal distribution. Bonferroni analysis was used for post hoc test. Statistical comparison of qualitative variables was performed using chi-square test. A p value < .05 was considered statistically significant.

RESULTS

A total of 766 patients (of which 350 underwent standard PCNL (group 1), 189 underwent tubeless PCNL with a DJ stent (group 2), and 227 underwent tubeless PCNL with an EUC (group 3)), were included in this study. The demographic parameter and stone characteristics are summarized in Table 1. There was no statistical difference in age, gender, and body mass index between the three groups. Most of the patients (59.9%) were male, and the gender distribution was also not statistically different between the three groups. The means of the body mass index between the three groups were within normal weight range with 24.85 ± 3.7 kg/m^2 in group 1, 24.45 ± 4.3 kg/m^2 in group 2, and 24.53 ± 3.8 kg/m^2 in group 3. The three groups also had comparable stone characteristic data. There was no significant difference in stone burden, surgery side, recurrent stone, history of kidney surgery, number of stones, location of stones, hydronephrosis, and type of anesthesia between the three groups.

Perioperative and postoperative characteristics between the three groups are shown in Table 2. The mean operative time between the three groups was not significantly different. Most of the PCNL procedures were done on the left kidney (52.7%) and with lower caliceal puncture access (91.6%). There was also no statistically significant difference in surgery side and puncture access approach between the three groups. Preoperative hemoglobin was significantly higher in group 1 (13.60 ± 1.9 g/dL) compared with group 2 (13.04 ± 2.0 g/dL), but not compared with group 3 (13.36 ± 1.7 g/dL). However, there was no statistically significant difference in hemoglobin drop after the PCNL procedures (Table 2). Preoperatively, group 3 had a significantly lower creatinine serum level of 1.24 ± 0.8 mg/dL compared with both group 1 (1.94 ± 2.2 mg/dL) and group 2 (1.82 ± 1.6 mg/dL). However, there was also no statistically significant difference of creatinine change after the PCNL procedures (Table 2).

The postoperative hospitalization period in group 1 was 4.12 ± 2.4 days, which was significantly longer than group 2 (3.44 ± 2.8 days; p < .001) and group 3 (3.19 ± 2.2 days; p < .001). However, the difference between group 2 and group 3 was not statistically significant (p = .680). The postoperative pain score in group 1 was 6.36±1.7 and significantly higher compared to that of group 2 (4.85 ± 1.1; p < .001) and group 3 (3.24 ± 1.1; p < .001). In post hoc analysis, the postoperative pain score in group 3 was also statistically significant when compared with group 2 (p < .001).

There were a total of 71 (9.3%) complications in this study (Table 3). The complication rates between standard, tubeless PCNL with a DJ stent, and tubeless PCNL with an EUC were comparable (9.7% vs. 9.5% vs. 8.4%, p = .854), as shown in Table 2. These groups also had comparable numbers of postoperative fever and blood transfusion (p > .05). However, there was a significant difference in postoperative urine leakage complications between these groups (p = .031). Postoperative urine leakage was significantly lower in group 3 (0.4%) compared with group 1 (2.9%, p = .038), but not statistically different to that of group 2 (0.5%, p = .897).

DISCUSSION

PCNL is the management procedure of choice for complex and large kidney stones owing to lower morbidity and shorter hospitalization compared with open kidney surgery.[17] The use of a nephrostomy tube at the end of the PCNL procedure is a common step to maintain adequate drainage, tamponade bleeding, provide access for a second-look procedure if necessary, and prevent urinary extravasation.[4,5] Despite these advantages, a nephrostomy tube leads to significant discomfort and pain for the patients.[18]

Technical improvements to avoid placement of a nephrostomy tube, especially for PCNL with the absence of residual stones or significant complication, has been advocated. Wickham *et al.* was the first to introduce a totally tubeless PCNL procedure in 1984.[19] A tubeless PCNL procedure using a ureteral stent instead of nephrostomy tube was introduced by Bellman *et al.* in 1997.[8] Goh and Wolf introduced a slightly modified tubeless PCNL technique that involves an EUC that can be removed after 1–2 days.[13] After that, there has been several reports of the use of an EUC instead of a DJ stent in tubeless PCNL to avoid stent-related discomfort and cystoscopy for removal.[10–12] In this study, we compared tubeless PCNL with an EUC, standard PCNL, and tubeless PCNL with a DJ stent following uncomplicated PCNL and the absence of a residual stone.

This study had a comparable basic demographic and stone-related characteristics between the three groups (Table 1). Although not statistically significant, there were more patients in standard PCNL group that had recurrent stones (21.4%; p = .060) and previous kidney surgery (80.9%; p = .066) compared to both PCNL with DJ stent and EUC groups. The mean stone burdens were more than 3 cm in all of the three groups. The differences were not statistically significant. The average size of the stone in this study was slightly bigger than that reported by Bhat *et al.,* who used size <3 cm as the inclusion criteria for PCNL.[18] The results of our study indicated that tubeless PCNL with an EUC is applicable for large and complex kidney stones with a size greater than 3 cm.

Although not statistically significant, the mean operative time for the tubeless PCNL with an EUC in this study was shorter compared with both standard PCNL and tubeless PCNL with a DJ stent. The longer time of the standard PCNL and tubeless PCNL with a DJ stent were likely owing to additional time for the placement of the nephrostomy tube or DJ stent. Meta-analysis by Chen *et al.* also found shorter operative times for tubeless PCNL with an EUC compared with a PCNL with a DJ stent, with a mean difference of 7.59 minutes, although it was not statistically significant.[11] These differences might be attributed to difference in the operative time criteria, patient characteristics, and surgeon's experience.

In this study, postoperative hospitalization period of the patients that underwent both tubeless PCNL with a DJ stent and an EUC were significantly shorter than those that underwent standard PCNL. However, the hospitalization period of the patients that underwent tubeless PCNL with an EUC and a DJ stent was not significantly different. This result was similar to the study by Gonen *et al.* and meta-analysis by Chen *et al.*, who found no difference in the hospitalization period between patients that underwent tubeless PCNL with an EUC and a DJ stent.[11,12] However, Singh *et al.* reported a significant difference in postoperative hospitalization between tubeless PCNL with an EUC and a DJ stent,[10] possibly owing to an aggressive discharge pattern by the operative surgeon. The longer hospitalization period of the patients that underwent standard PCNL may be attributed to the higher pain score and the requirement of additional procedures for the removal of the nephrostomy tube.

In this study, the postoperative pain score on POD1 measured by VAS of patients in group 3 was significantly lower than those in group 1 and group 2. Singh *et al.* reported a similar result with less stent-related symptoms and analgesia requirement in patients that underwent tubeless PCNL with an EUC.[10] A higher VAS score in group 1 and group 2 may be attributed to the nephrostomy tube size and stent discomfort caused by a DJ stent. A psychological effect of knowing that EUC will be removed before discharge may also contribute to lower perception of pain in group 3. A lower pain score following tubeless PCNL with an EUC reduces analgesia demand, hospital cost, and fastens the recovery time.[10]

Intra-operative anesthesia also affects the postoperative pain score. Basiri *et al.* found that spinal anesthesia does not provide enough analgesia for the patient in a limited frequency of PCNL surgery.[20] Contrary, Solakhan *et al.* found that spinal anesthesia is a safe, effective, and low-cost method for PCNL surgery. Post-operative analgesic requirements also significantly less in spinal anesthesia group compared to general anesthesia group.[21] In this study, most of the PCNL procedures were performed with spinal anesthesia. There was no significant difference of the type of anesthesia between the three groups.

This study showed comparable complication rates in patients that underwent standard PCNL, tubeless PCNL with a DJ stent, and tubeless PCNL with an EUC. This result was similar to several studies.[11,17] This result may be owing to strict sample selection with no congenital anomaly, no significant intraoperative hemorrhage, and no significant collecting system injury. In addition, many new techniques have recently been employed to anticipate urine leakage and postoperative bleeding in the absence of an indwelling nephrostomy tube.[22]

One of the most significant complication of PCNL is bleeding. Although the use of a nephrostomy tube following PCNL aimed to assist in hemostasis,[9] there was no significant difference in hemoglobin drop and transfusion rate across the three groups in this study. Meta-analysis by Chen *et al.* described the changes in hemoglobin were uniform in patients that underwent tubeless PCNL with a DJ stent and tubeless PCNL with an EUC.[11] However, when only randomized controlled trials were assessed, this meta-analysis found higher hemoglobin drops in patients that underwent tubeless PCNL with a DJ stent in a postoperative setting.[11] This might be attributed to hematuria as an early complications in 13.6% of cases after tubeless PCNL with a DJ stent.[23] Stone opacity in plain radiography also affects the bleeding complication. Maghsoudi *et al.* found that PCNL of radiolucent stones will lead to significantly higher bleeding rate compared to radiopaque stones.[24] However our study didn't have enough data of stone opacity between the three groups.

In our study, the occurrence of fever between the three groups was not statistically different. This was similar to the meta-analysis by Xun *et al.*, Chen *et al.*, and Borges *et al.*[11,22,25] Fever, which is mostly observed in the first two days postoperatively, has a low risk to progress to a life-threatening condition.[18] The fever complication rate in this study was only 2.6–3.2% owing to the use of prophylactic antibiotics and strict inclusion criteria in this study. Moreover, tubeless PCNL could significantly decrease postoperative urinary leakage complications compared with standard PCNL. Most of the patients with urine leakage complications had a nephrostomy tube inserted for obstruction diversion preoperatively. A well-formed nephrostomy tract needs time to heal, resulting in urinary extravasation in the absence of a nephrostomy tube.[26]

This study has several limitations. One limitation is the retrospective nature of this study. However, the data was recorded and collected in a detailed manner. Furthermore, the PCNL procedures were conducted by three different main surgeons. However, the three surgeons had a similar technique, good experience, and a comparable skill level. Our study also didn't evaluate analgesic requirement between the three groups for postoperative pain score comparison because of incomplete data. The stent-related discomforts from DJ stent and EUC were also likely to be overlooked because it was felt over the urethra or suprapubic region, instead of the flank region.[27,28] VAS score has not been the method of choice for measuring stent-related discomforts.[27] The retrospective nature of this study fail to ensure accurate measurement of stent-related symptoms and their contribution to the postoperative discomfort following PCNL surgery.

CONCLUSIONS

Tubeless PCNL is an effective and safe procedure for uncomplicated PCNL in the absence of residual stones. This approach has a complication rate that is comparable with standard PCNL. Tubeless PCNL with an EUC is associated with decreased pain, hospitalization time, and urine leakage complication compared with standard PCNL. When compared with tubeless PCNL with a DJ stent, tubeless PCNL with an EUC is only associated with decreased pain.

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None.

CONFLICT ON INTEREST

None.

ETHICAL STANDARDS

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975 (in its most recently amended version). Collected data were obtained from the patients' medical records. Our institutional ethics committee has accepted this study protocol (0553/UN2.F1/ETIK/2018).

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Tables:

Table 1. Patient and stone characteristics

Variables[a]	Standard PCNL (group 1; N=350)	Tubeless PCNL with DJ stent (group 2; N=189)	Tubeless PCNL with EUC (group 3; N=227)	*P*-value
Age (years)	51.19 ± 10.4	50.34 ± 11.6	50.79 ± 11.2	.794
Body Mass Index (kg/m^2)	24.85 ± 3.7	24.45 ± 4.3	24.53 ± 3.8	.358
Stone burden (mm)	35.53 ± 17.9	36.10 ± 22.1	33.47 ± 17.2	.149
Gender:				.499
Male	207 (59.1%)	120 (63.5%)	132 (58.1%)	
Female	143 (40.9%)	69 (36.5%)	95 (41.95)	
Recurrence:				.060
First-time	275 (78.6%)	164 (86.8%)	187 (20.4%)	
Recurrent	75 (21.4%)	25 (13.2%)	40 (17.6%)	
Previous kidney surgery:				.066
Yes	67 (19.1%)	24 (12.7%)	30 (13.2%)	
No	283 (80.9%)	165 (87.3%)	197 (86.8%)	
Number of stones:				.166
1 stone	217 (62.0%)	106 (56.1%)	153 (67.4%)	
2 stones	70 (20.0%)	49 (25.9%)	47 (20.7%)	
3 stones	35 (10.0%)	18 (9.5%)	16 (7.0%)	
4 stones	8 (2.3%)	7 (3.7%)	7 (3.1%)	
> 4 stones	20 (5.7%)	9 (4.8%)	4 (1.8%)	
Location of stones:				.173
Caliceal	100 (28.6%)	53 (28%)	63 (27.8%)	
Pelvic	101 (28.9%)	61 (32.3%)	71 (31.3%)	
Pelvis + caliceal	148 (42.3%)	72 (38.1%)	85 (37.9%)	
Upper ureter	1 (0.3%)	3 (1.6%)	7 (3.1%)	
Hydronephrosis:				.116
Yes	176 (50.3%)	84 (44.4%)	95 (41.9%)	
No	174 (49.7%)	105 (55.6%)	132 (58.1%)	
Anesthesia:				.711
General	287 (82.0%)	154 (81.5%)	180 (79.3%)	
Spinal	63 (18.0%)	35 (18.5%)	47 (20.7%)	

Abbreviations: BMI: body mass index; DJ: double J; EUC: externalized ureteral catheter; kg: kilogram; m^2: meter square; mm: millimeter; PCNL: percutaneous nephrolithotomy.

[a] Continuous variables were compared by either one way ANOVA test or Kruskal-Wallis test. Qualitative variables were compared by chi-square test.

Table 2. Perioperative and postoperative characteristic

Variables[a]	Standard PCNL (group 1; N=350)	Tubeless PCNL with DJ stent (group 2; N=189)	Tubeless PCNL with EUC (group 3; N=227)	*P*-value
Mean operative time (mins)	66.22 ± 28.3	67.76 ± 28.4	63.11 ± 24.8	.445
Surgery Side:				.750
Right	163 (46.6%)	87 (46.0%)	112 (49.3%)	
Left	187 (53.4%)	102 (54.0%)	115 (50.7%)	
Puncture access approach:				.199
Lower caliceal	328 (93.7%)	167 (88.4%)	207 (91.2%)	
Middle caliceal	11 (3.1%)	11 (5.8%)	13 (5.7%)	
Upper caliceal	11 (3.1%)	11 (5.8%)	7 (3.1%)	
Postoperative hemoglobin change (g/dL)	-1.05 ± 1.2	-0.97 ± 1.3	-0.89 ± 1.2	.119
Postoperative creatinine change (mg/dL)	0.32 ± 0.4	0.26 ± 0.3	0.34 ± 0.4	.130
Postoperative hospitalization (days)	4.13 ± 2.4	3.44 ± 2.8	3.19 ± 2.2	**< .001**
Postoperative pain score (VAS)	6.36 ± 1.7	4.85 ± 1.1	3.24 ± 0.8	**< .001**
Postoperative complication	34 (9.7%)	18 (9.5%)	19 (8.4%)	.854
Postoperative blood transfusion	12 (3.4%)	8 (4.2%)	7 (3.1%)	.811
Postoperative fever	11 (3.1%)	6 (3.2%)	6 (2.6%)	.931
Postoperative urine leakage	10 (2.9%)	1 (0.5%)	1 (0.4%)	**.031**

Abbreviations: DJ: double J; EUC: externalized ureteral catheter; g/dL: gram/deciliter; mins: minutes; mg/dl: milligram/deciliter; PCNL: percutaneous nephrolithotomy; VAS: visual analog scale.

[a] Continuous variables were compared by either one way ANOVA test or Kruskal-Wallis test. Bonferroni analysis was used for post hoc test. Qualitative variables were compared by chi-square test.

Table 3. Complications classified by a modified Clavien system

Variables[a]	Standard PCNL (group 1; N=350)	Tubeless PCNL with DJ stent (group 2; N=189)	Tubeless PCNL with EUC (group 3; N=227)
Grade I			
Postoperative fever	11 (3.1%)	6 (3.2%)	6 (2.6%)
Peri-nephrostomy urinary leakage <24 hours	4 (1.1%)	—	—
Wound infection	—	—	1 (0.4%)
Grade II			
Blood transfusion	12 (3.4%)	8 (4.2%)	7 (3.1%)
Grade IIIA			
Prolonged urinary leakage	6 (1.7%)	1 (0.5%)	1 (0.4%)
Retention due to blood clots	—	1 (0.5%)	2 (0.9%)
Infundibular stenosis	1 (0.3%)	—	1 (0.4%)
Perinephric abscess	—	1 (0.5%)	—
Pyonephrosis	—	—	1 (0.4%)
Grade IVB			
Sepsis	—	1 (0.5%)	—
Total	34 (9.7%)	18 (9.5%)	19 (8.4%)

Abbreviations: DJ: double J; EUC: externalized ureteral catheter; PCNL: percutaneous nephrolithotomy.

[a] Qualitative variables were compared by chi-square test.