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Percutaneous nephrostomy in cervical cancer patients: a retrospective analysis

Nefrostomia percutânea em pacientes com câncer cervical: uma análise retrospectiva

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ABSTRACT

Objectives: To evaluate the outcome of patients with cervical carcinoma submitted to percutaneous nephrostomy due to malignant ureteral obstruction. **Material and Methods:** Retrospective cohort study with data obtained from medical records of patients diagnosed with cervical carcinoma with renal dysfunction (AKIN = stage 2) undergoing PCN for malignant obstructive uropathy between January 2019 and December 2020 at a tertiary hospital in Recife, Brazil. **Results:** We evaluated 31 patients submitted to percutaneous nephrostomy. Median age was 50 years, and the majority of women were non-white with an elementary education. Twenty-one patients required hemodialysis before the procedure, and 61.9% of them recovered renal function after nephrostomy. Bleeding and nephrostomy tube displacement were the leading causes of complications in the first 30 days (69%). Median overall survival after the procedure was 8.7 months. Survival was significantly worse in patients with anemia, ECOG performance status = 2 (p=0.04), pre-nephrostomy dialysis (p=0.01), and not recovery of renal function after PCN. **Conclusions:** Performing urinary diversion through percutaneous nephrostomy seems to offer greater benefits in patients with better functionality. Given the morbidity and complications inherent to percutaneous nephrostomy, the profile of patients who benefit most from the procedure remains unclear. Referrals for the procedure must be individualized and consider the patient's desire, treatment perspectives, and functionality.

Keywords: Uterine cervical neoplasms; Hydronephrosis, Ureteral obstruction; Urinary diversion; Nephrostomy, Percutaneous.

RESUMO

Objetivos: Avaliar a evolução de pacientes com carcinoma cervical submetidos à nefrostomia percutânea por obstrução ureteral maligna. **Material e Métodos:** Estudo de coorte retrospectivo com dados obtidos de prontuários de pacientes diagnosticados com carcinoma cervical com disfunção renal (AKIN = estágio 2) submetidos à nefrostomia percutânea por uropatia obstrutiva maligna entre janeiro de 2019 e dezembro de 2020, em um hospital terciário em Recife, Brasil. **Resultados:** Avaliamos 31 pacientes submetidos à nefrostomia percutânea. A idade média foi de 50 anos, e a maioria das mulheres não eram brancas com ensino fundamental. Vinte e um pacientes necessitaram de hemodiálise antes do procedimento, e 61,9% deles recuperaram a função renal após a nefrostomia. Sangramento e deslocamento do tubo de nefrostomia foram as principais causas de complicações nos primeiros 30 dias (69%). A sobrevida global mediana após o procedimento foi de 8,7 meses. A sobrevida foi significativamente pior em pacientes com anemia, escala de desempenho ECOG = 2 (*p*=0,04), diálise pré-nefrostomia (*p*=0,01) e não recuperação da função renal após nefrostomia percutânea. **Conclusões:** A realização da derivação urinária por nefrostomia percutânea parece oferecer maiores benefícios em pacientes com melhor funcionalidade. Dada a morbidade e as complicações inerentes à nefrostomia percutânea, o perfil dos pacientes que mais se beneficiam com o procedimento permanece incerto. O encaminhamento para o procedimento deve ser individualizado e levar em consideração o desejo do paciente, as perspectivas de tratamento e a funcionalidade.

Descritores: Neoplasias do colo do útero; Hidronefrose, Obstrução ureteral; Derivação urinária; Nefrostomia percutânea.

INTRODUCTION

Cervical cancer is considered a public health problem. It is the fourth most common cause of cancer among women worldwide and projected to increase from 570,000 to 700,000 cases between 2018 and 2030. The annual mortality rate is projected to increase from 311,000 to 400,000.[1] In Brazil, it represents the third cause of cancer in women (incidence 15.38 cases per 100,000 inhabitants) and the third cause of cancer death (4.6 cases per 100,000 inhabitants).[2]

The International Federation of Gynecology and Obstetrics (FIGO) classification is used for disease staging. Stage III-B corresponds to invasion into the pelvic wall, hydronephrosis, or a non-functioning kidney.[3] The literature shows that the 5-year overall survival of women treated in this stage is 41.5%.[4]

Currently, the proposed therapy for locally advanced cervical cancer patients is radiation therapy (RT), concomitant with cisplatin-based chemotherapy (CT). Cisplatin is a chemotherapeutic agent that can potentially cause acute tubular necrosis and result in renal failure and is often not prescribed to patients with preexisting renal dysfunction (i.e., GFR<50-60ml//min/1.73m^2).[5]

In locally advanced stages IIIB, IIIC2, and IVA, clinical studies have demonstrated that unilateral and bilateral hydronephrosis are predictors of mortality and poor prognostic factors for survival. Urinary diversion procedures using percutaneous nephrostomy (PCN) or ureteral stents are available options for such cases.[6,7]

It remains unclear whether urinary diversion procedures improve the overall patient survival rate. Many studies are relatively old, from small cohorts, and outdated.[6,8] The literature does mention authors who performed interventions and observed good results in stages IIIB-IVA patients. Even so, others demonstrated no significant effects on survival rates, especially in the palliative cases of recurrent or metastatic disease.[9-11]

This study aims to determine the overall survival rates of cervical cancer patients undergoing PCN for malignant ureteral obstruction, as well as to analyze clinical variables associated with survival and to describe complications related to the procedure.

MATERIAL AND METHODS

Study population

This is a retrospective, cross-sectional and observational study. Data were obtained from medical records of patients with cervical cancer undergoing PCN due to malignant obstructive uropathy between January 2019 and December 2020 at Hospital *Barão de Lucena* in Recife, Pernambuco (PE), Brazil.

We included patients with invasive cervical uterine malignancy (at least stages IIIB) with unilateral or bilateral hydronephrosis and renal dysfunction (AKIN stage ≥2) submitted to PCN at the time of diagnosis of neoplasia, disease progression or recurrence after previous definitive treatment.

Patients without anatomopathological biopsy results, ureteral obstruction caused by other diseases and loss of follow-up were excluded from this study.

The main objective was to estimate overall survival of these patients, defined as the date between the procedure and death. Secondary objectives were: (1) to evaluate the morbidity and complications of PCN and (2) to identify variables associated with survival.

The *Centro Integrado de Saúde Amaury de Medeiros* (CISAM/UPE) ethics and research committee approved the project under CAAE number 50399421.0.0000.5191, per Brazilian National Health Council Resolutions 466/12 and 510/16.

Statistical analysis

Sociodemographic, clinical-laboratory, oncological, and survival-related variables were determined. A data collection form (Appendix 1) was used to gather data from the medical records of each selected patient, and an Excel spreadsheet was created.

Qualitative variables were expressed as absolute and relative values and quantitative variables as mean, median, standard deviation, minimum, and maximum statistics. The assumed significance level was 5%. Statistical analyses were performed using SPSS – Statistical Package for Social Sciences for Windows, version 21.0.

The Kaplan-Meier estimator was used to estimate survival probability. It was first analyzed globally with no stratification. Then, it was analyzed with stratification by the covariates determined during the study. The log-rank test was used to compare survival curves according to the categories of covariates studied.

A Cox Proportional Hazards Model was adjusted to analyze the time-to-event factors considering all variables contemporaneously. The model only included covariates that were associated with a mortality rate with a significance level lower than 0.20 in the bivariate analysis.

RESULTS

Thirty-one (n=31) cervical cancer patients undergoing PCN were evaluated. The median age was 50 (range; 23-77 years). Race was defined as non-white in 21 patients. Most women (67.7%) studied up to elementary school. Table 1 shows the sociodemographic characteristics.

The most frequent histological subtype was squamous cell carcinoma (80.6%). Most patients were submitted to the procedure at the time of initial diagnosis (n=17) and had a performance

Table 1. Sociodemographic characteristics of the patients.

Variables	N = 31
AGE (years)	
Mean (SD)*	48.9 (14.1)
Median (minimum – maximum)	50 (23 – 77)
AGE	
<50 years	15 (48.4%)
≥50 years	16 (51.6%)
COLOR	
White	10 (32.3%)
Non-White	21 (67.7%)
MARITAL STATUS	
Married/Common-Law	13 (41.9%)
Marriage	15 (48.4%)
Single / Widow / Divorced	3 (9.7%)
Not disclosed	
EDUCATION	
Up to Elementary School	21 (67.7%)
High School	3 (9.7%)
Not disclosed	7 (22.6%)
OCCUPATION	
Paid activity	14 (45.2%)
No paid activity	11 (35.5%)
Not disclosed	6 (19.4%)
RESIDENCE	
Recife	16 (51.6%)
Countryside	15 (48.4%)
SMOKER	
No	14 (45.2%)
Yes	11 (35.5%)
Not disclosed	6 (19.4%)

status ≥2 (61,3%, n=19). Table 2 presents the clinical characteristics of the sample.

Mean serum hemoglobin (Hb) was 7.8g/dL, mean pre-procedure creatinine was 5.2mg/dL, and mean pre-procedure albumin was 2.8g/dL. The clinical and laboratory characteristics are shown in Table 3.

The mean length of hospital stay for the procedure was 17.9 days, with a 69% complication rate in the first 30 days. The most frequent complications were bleeding (15 events) and nephrostomy tube displacement (7 events). Twenty patients have died. Main cause of death included uremia and septic shock. Table 4 displays complications and outcomes.

The median overall survival was 8.7 months (261 days, 95% CI: 157-365), as expressed in Figure 1. ECOG-PS ≥2 was significantly associated with poor survival (3.4 months *vs.* 13 months, *p*=0.047) as shown in Figure 2.

Twenty-one (21) patients required pre-nephrostomy HD, and 13 patients recovered renal function after urinary diversion. Patients who underwent HD had statistically significant worse survival (2.7 *vs.* 13 months, *p*-value of 0.01, Figure 3).

Table 2. Clinical characteristics of the patients.

Variables	N = 31
HISTOLOGICAL TYPE	
SCC	25 (80.6%)
Adenocarcinoma	2 (6.5%)
Carcinosarcoma	1 (3.2%)
Not specified	3 (9.7%)
TIME FROM DIAGNOSIS	
<12 months	26 (83.9%)
≥12 months	5 (16.1%)
STAGING AT DIAGNOSIS	
II-A	1 (3.2%)
II-B	5 (16.1%)
III-B	6 (19,3%)
III-C	3 (9.7%)
IV-A	11 (35.5%)
IV-B	5 (16,1%)
PRIOR TREATMENT	
Surgery	1 (3,2%)
CT+RT	14 (45.2%)
Exclusive CT	1 (3.2%)
Surgery+CT+RT	1 (3.2%)
None	14 (45,2%)
DISEASE STATUS (n=31)	
Initial diagnosis	17 (54,8%)
Local/Regional Recurrence,	8 (26.7%)
Local recurrence and distant metastasis	6 (20.0%)
SITES OF METASTASIS (n=11)	
Lung	3 (27.3%)
Liver	4 (36.4%)
Central nervous system	1 (9.0%)
Lung + Bone + Liver	1 (9.0%)
Lung+Bone	2 (18,3%)
BILATERAL PCN	22 (71.0%)
HD PRE-NEPHROSTOMY	21 (67.7%)
HD-FREE POST-NEPHROSTOMY (n=21)	13 (61.9%)
Eastern Cooperative Oncology Group Performance Status (ECOG-PS)	
0-1	12 (38.7%)
≥2	19 (61.3%)

Patients who recovered renal function and remained HD-free had a statistically significant better survival compared with those who did not, with a *p*-value of 0.01 (Figure 4).

Patients with hemoglobin lower than 10g/dL had a statistically significant worse survival when comparing with patients with Hb≥10g/dL, (3.1 *vs.* 13 months, *p*-value of 0.01, Figure 5).

Multivariate analysis found that patients with ECOG-PS ≥2 are approximately four times more likely to die than patients with an ECOG-PS 0-1. Patients who underwent pre-nephrostomy HD are approximately 3.7 times more likely to die than patients without pre-procedure HD, as seen in Table 5.

DISCUSSION

Despite having efficient methods for prevention and early diagnosis, cervical cancer is a challenging public health problem for developing countries. [12] Malignant ureteral obstruction develops in a substantial proportion of patients, reaching almost a quarter of them at some point in the course of the disease and is considered a poor prognostic factor. [13,14]

Several studies have shown that urinary diversion can improve renal function in cervical cancer patients, although the effects of the procedure on overall survival rates are unclear. [8,9,13]

Table 3. Laboratory Characteristics.

Variables	N = 31
HYPERCALCEMIA (n=22)	6 (27.3%)
PRE-NEPHROSTOMY PLATELETS (/mm^3)	
Mean (SD)	358,032.3 (136,440)
Median (minimum – maximum)	371,000 (60,000 – 645,000)
PLATELETS (/mm^3)	
≤400,000	19 (61.3%)
>400,000	12 (38.7%)
PRE-NEPHROSTOMY HEMOGLOBIN (g/dL)	
Mean (SD)	7.8 (2.3)
Median (minimum – maximum)	7.5 (3.9 – 13.8)
Creatinine PRE-NEPHROSTOMY (mg/dL)	
Mean (SD)	5.2 (2.8)
Median (minimum – maximum)	5.2 (1.1 – 12)
ALBUMIN PRE-NEPHROSTOMY (n=24)	
Mean (SD)	2.8 (0.6)
Median (minimum – maximum)	2.8 (1.7 – 4.2)
NEUTROPHIL/LYMPHOCYTE RATIO (n=30)	
Mean (SD)	10.4 (7.0)
Median (minimum – maximum)	7.3 (2.6 – 32.3)

Table 4. Complications and outcomes.

Variables	N = 31
DAYS IN HOSPITAL POST-NEPHROSTOMY (n=30)	
Mean (SD)	17.9 (13.8)
Median (Minimum – Maximum)	14.5 (1 – 62)
30-DAY COMPLICATION RATE (n=31)	20 (69.0%)
TYPE OF COMPLICATION (10 patients presented > 1 complication)	
Bleeding	15 (48,4%)
Nephrostomy tube displacement	7 (22,6%)
Pain	4 (12,9%)
UTI	5 (16,1%)
ANTINEOPLASTIC TREATMENT POST-NEPHROSTOMY	19 (61.3%)
Cause of death (n=20)	
UTI	1 (5.0%)
DVT-PE	1 (5.0%)
Bronchoaspiration	1 (5.0%)
Bowel obstruction	2 (10.0%)
Uremic syndrome	4 (20.0%)
Acute Resp. Failure	3 (15.0%)
Septic shock	4 (20.0%)
Liver Failure	1 (5.0%)
No defined cause	3 (15.0%)

Six patients of the sample (16,1%) were on stage IVB but only 3.2% received palliative chemotherapy. This data must be correlated with progression of disease, complications of procedure and infectious disorders.

It was also found that 54,8% of the sample comprised newly diagnosed patients; 26.7% were local-regional recurrences, and 20% were local and distant recurrences. That data corroborates that the diagnosis is still made late and, most often, in the presence of a severe complication such as malignant ureteral obstruction.[9]

Median survival in our study was 8.7 months. Comparison with other studies is difficult, as most of them were performed with a limited number of patients. Most studies found a median overall survival of 8.9 to 34 weeks.[6,7,9,10] This difference in survival may be attributed to patient characteristics, as 54.8% of our sample comprised newly diagnosed patients. In a Brazilian study with 50 patients,
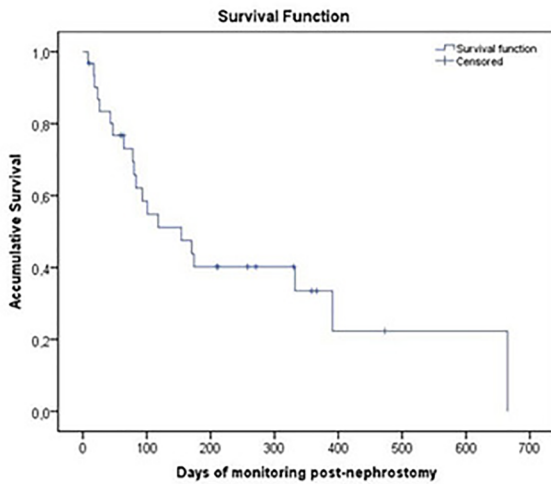
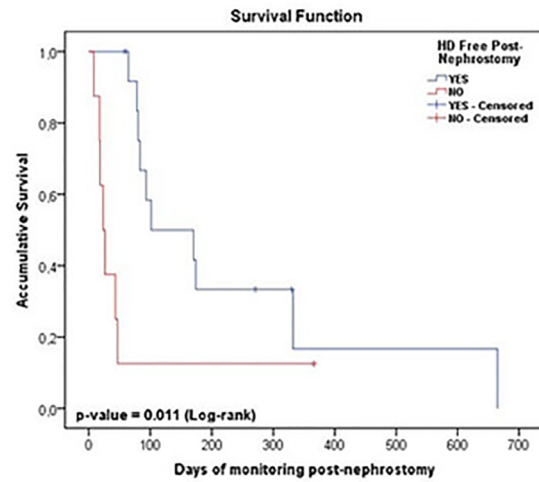Figure 1. Overall survival curve of the sample studied.

Figure 4. Survival curve per recovery of renal function post-nephrostomy.
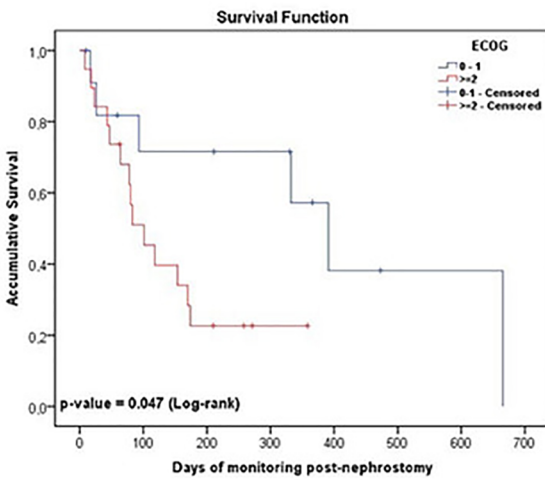

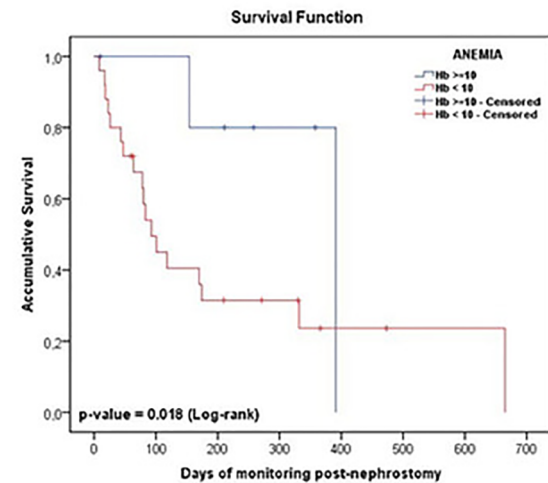Figure 2. Survival curve per performance status.
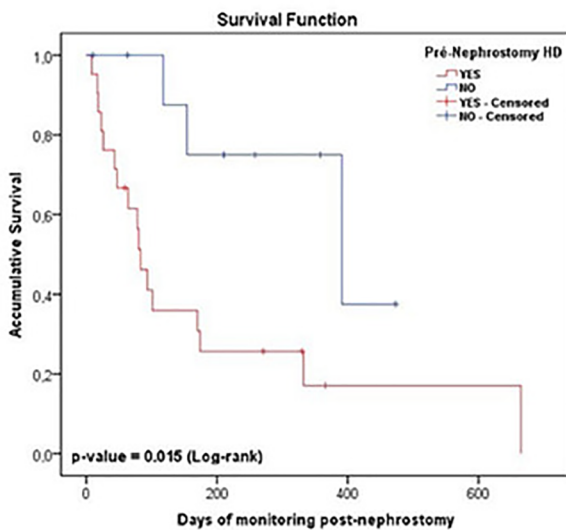

Figure 5. Survival curve per anemia.

Figure 3. Survival curve per pre-nephrostomy HD.

median survival was only 8.9 weeks, but all patients had received previous treatment and were receiving palliative care at the time of PCN.[9]

Twenty-one patients required renal replacement therapy before PCN (67.7%), with 13 patients fully recovering renal function and free of HD (61.9%). These findings are consistent with the literature, which has shown that among those patients requiring HD, 61.7% of them recovered renal function after the obstruction was cleared.[15]

There were complications in 69% of the patients, with bleeding and nephrostomy tube displacement being the most prevalent. This finding is similar to those of a German study with 24 patients, which identified that 13 patients experienced bleeding after PCN (54%). [9] Plesinac-Karapandzic et al. (2010)[16] found a rate of complications of 53.85% in 117 women submitted to PCN for gynecological malignancies, and tube displacement was the most frequent.[16]

Table 5. Survival Analysis Result - Cox Regression Model

Variables	Multivariate	
	RR (CI 95%)	*p*-value
ECOG (≥2 x 0-1+)	4.17 (1.19 – 14.52)	0.025
Pre-nephrostomy HD (Yes x No+)	3.70 (1.11 – 12.30)	0.033
Anemia (Yes x No+)	Ns	Ns

RR: Relative Risk; CI: Confidence Interval; +: Category considered as a reference category; Ns: Not significant (excluded from the final model, as they did not show any statistical significance *p*>0.05).

The mean post-PCN hospital stay was 17.9 days, a discrepant result from that found by Tan et al. (2019)[17] (3.2 days). The longer hospitalization time found in our study could be justified by the fact that the service only performs the procedure two shifts per week in the interventional radiology sector.

The leading causes of death (20 patients) in our study were septic shock and uremic syndrome. Eleven deaths were related to progression of disease and four deaths due to complications of PCNs.

Variables associated with shorter survival in our study were poor performance status, hemoglobin level <10g/dL, need of HD pre nephrostomy and not recovery of renal function after PCN. For anemia, erythropoietin has not been used as therapy. These findings are consistent with the literature.[9,11,15,18,19]

Disease status at the time of PCN, platelet and calcium levels and neutrophil/lymphocyte ratio were not associated with survival in our study, probably due to the small sample size. Some studies have used the neutrophil/lymphocyte ratio for evaluation as a prognostic tool for patients with invasive cervical cancer, based on the hypotheses of cancer-induced elevation of inflammatory cytokines promoting angiogenesis, invasion, and hematogenous dissemination.[20-22] Our sample had a mean neutrophil/lymphocyte ratio of 10.4 which is considered a very high level, but statistical analyses of survival comparing patients above and below this cut-off did not show a meaningful difference.

The strength of our study is that this is the first data on this subject in patients in the northeast of Brazil, assessing the sociodemographic factors and the overall survival rate after PCN, describing the procedure's inherent morbidity, and evaluating possible factors associated with survival.

This study also has limitations. This is a retrospective and descriptive cohort study with a small sample size without a control arm. The absence of a post-procedure quality of life assessment makes it impossible to measure functionality, autonomy, and mental health after PCN. Sample selection bias is another limitation. As the study was developed in a tertiary hospital with HD clinic, there is a tendency to have more patients on HD (67.7% of the sample).

We conclude that patients with cervical carcinoma requiring PCN have a poor outcome with a median survival of 8.7 months in this study. ECOG-PS ≥2, Hb<10g/dL), renal failure with need of HD and not recovery of renal function after PCN adversely affect survival rates. These results clearly demonstrate that referrals for the procedure must be individualized based on patient's desire, treatment perspectives, and functionality, since there are no clear guidelines to help us to select which patients can benefit from this procedure.

AUTHORS' CONTRIBUTIONS

DPAL	Collection and assembly of data, Conception and design, Manuscript writing
CNMT	Conception and design, Data analysis and interpretation, Final approval of manuscript
MBA	Collection and assembly of data, Provision of study materials or patient
FANR	Conception and design, Final approval of manuscript
SBF	Final approval of manuscript

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APPENDIX 1

Data collection

1. **Data and sociodemographic variables:**

- Medical register number: _____

- Age at the time of performing the nephrostomy (in years): _____

- Categorized age: < 50 years (   ) / ≥ 50 years (   )

- Color: White (   ) / Non-White (   )

- Marital status: Married/Common-Law (   ) / Single / Widow / Divorced /Not disclosed (   )

- Education: ≤ Up to Elementary School (   ) / High School (   ) / Higher education level (   ) / Not disclosed (   )

- Occupation: Paid activity - Yes (   ) / No (   ) / Not disclosed (   )

- Residence: Recife (   ) / Countryside (   )

- Smoker: Yes (   ) /   No (   ) / Not disclosed (   )

- Comorbities: Yes (   ) / No (   ). Which are they?: _____

2. **Oncological variables:**

- Date of diagnosis of cervical cancer: date of first biopsy with confirmed invasive disease _____

- Histological type: SCC (   ) / Adenocarcinoma (   ) / Carcinosarcoma (   ) /

Not disclosed (   )

- Diagnosis time and performance of nephrostomy: ≤ 12 months (   ) / > 12 months (   ).

- Diagnosis stage: I (   ) / IIA (   ) / IIB (   ) / IIIA (   ) / IIIB (   ) /IIIC (   ) /IVA (   )/ IVB (   )

- Prior treatment: Surgery (   ) / Exclusive Radiotherapy (   ) / Radiochemotherapy (   ) / Exclusive Chemotherapy (   ) None (   )

- Disease status: Initial diagnosis (   ) / Local/Regional Recurrence (   ) / Local recurrence and distant metastasis (   )

- Metastasis sites: _____

- Eastern Cooperative Oncology Group Performance Status (ECOG-PS) at the time of performing the nephrostomy: 0 (   ) /1 (   ) / 2 (   ) /3 (   ) /4 (   )

3. **Variables and data related to ureteral obstruction:**

- Date of nephrostomy: _____

- Bilaterality: Yes (   ) / No (   )

- Creatinine pre-nephrostomy (mg/dL):

- Hemodialysis pre-nephrostomy: Yes (   ) / No (   ) – If positive, describe if recover renal function and stop dialysis: Yes (   ) / No (   )

- Leukocytes pre- nephrostomy: _____

- Lymphocytes pre- nephrostomy: _____

- Platelets pre- nephrostomy: _____

- Hemoglobin pre- nephrostomy: _____

- Albumin pre- nephrostomy: _____

- Hypercalcemia pre- nephrostomy: Yes (   ) / No (   ) / Not disclosed (   )

- Performed cancer-treatment after performing nephrostomy: Yes (   ) / No (   )

- Length of hospital stay after performing nephrostomy: _____

- Need for readmission in the first year after procedure: Yes (   ) / No (   ). If positive, what is the reason? _____.

How many hospitalizations in the first year after nephrostomy: _____

- Complications in the first 30 days after nephrostomy: Yes (   ) / No (   ). If positive: Bleeding ( ) / Urinary tract infection ( ) / Nephrostomy obstruction (   ) / Nephrostomy loss (   ) /Others: _____

4.   Survival

- Last follow-up date: _____

- Time between performing nephrostomy and date of last follow-up (in days): _____

- Status at last follow-up: Living without disease (   ) / Living with disease (   ) / Death ( ). Cause of death: _____