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RESEARCH ARTICLE

Surgical aspects and outcomes after nephrectomy for Wilms tumour in sub-Saharan Africa: A report from Wilms Africa Phase II—CANCaRe Africa

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Abstract

Background: Wilms tumour (WT) is one of the common and curable cancer types targeted by the Global Initiative for Childhood Cancer. Tumour excision is essential for cure. This analysis focuses on surgical outcomes of patients with WT in sub-Saharan Africa.

Methods: We implemented a risk-stratified WT treatment guideline as a multicentre, prospective study across eight hospitals and six countries. Eligibility criteria were age

Abbreviations: CANCaRe Africa, Collaborative African Network for Childhood Cancer Care and Research; CRF, case report form; EFS, event-free survival; EOT, end of treatment; GICC, Global Initiative for Childhood Cancer; OS, overall survival; SIOP, International Society of Paediatric Oncology; WT, Wilms tumour.

6 months to 16 years, unilateral WT, surgery performed after preoperative chemotherapy and diagnosed between 1 January 2021 and 31 December 2022. Data collection included a specific surgical case report form (CRF).

Results: The study registered 230 patients, among whom 164 (71.3%) had a nephrectomy. Ninety-eight percent of patients had a completed surgical CRF. Out 164 patients, 50 (30.5%) had distant metastases. Median tumour diameter at surgery was 11.0 cm. Lymph node sampling was done in 122 (74.3%) patients, 34 (20.7%) had intraoperative tumour rupture, and for 18 (10.9%), tumour resection involved en bloc resection of another organ. Tumour size at surgery was significantly correlated with tumour rupture ($p < .01$). With a median follow-up of 17 months (range: 2–33), 23 (14.0%) patients have relapsed. Twenty-two (13.4%) patients abandoned treatment post nephrectomy. Two-year event-free survival was 60.4% ± 4.7% with treatment abandonment as an event.

Conclusion: Survival post nephrectomy is challenged by treatment abandonment, treatment-related mortality and relapse. Large tumours after preoperative chemotherapy were associated with a higher risk of tumour rupture. Earlier diagnosis and access to radiotherapy are expected to improve survival.

KEYWORDS
Africa, nephrectomy, nephroblastoma, resource-limited settings, surgery, survival, Wilms

1 | INTRODUCTION

Wilms tumour (WT) is one of the common and curable childhood cancers targeted by the Global Initiative for Childhood Cancer (GICC).[1] WT overall survival (OS) in high-income countries is over 90%.[2] Reported event-free survival (EFS) in sub-Saharan Africa is below 50%.[3–7] Challenges to survival in sub-Saharan Africa include late presentation with advanced disease, treatment abandonment and treatment-related mortality.[8–10]

The primary role of surgery in the multimodality management of WT is to remove the tumour completely without spillage and to assist in the staging and risk stratification by appropriate lymph node sampling. Effective communication of the assessment of loco-regional spread to the multidisciplinary team is crucial.

Use of preoperative chemotherapy is recommended in sub-Saharan Africa.[11] In this setting, patients often present with large tumours, supportive care is limited and radiotherapy often not available.[8,9,11] Preoperative chemotherapy shrinks the tumour and reduces the risk of intraoperative tumour rupture, thereby reducing the need for very intense postoperative treatment or radiotherapy.[12]

Wilms Africa Phase I implemented a consensus SIOP (International Society of Paediatric Oncology) Global Health Network WT treatment guideline adapted to local circumstances in four hospitals in sub-Saharan Africa.[13,14] The protocol was based on local evidence from Blantyre, Malawi and the protocol of the SIOP Renal Tumour Study Group (RTSG).[11] Preoperative chemotherapy was recommended for all patients over 6 months of age.[11] Adjustments made to the SIOP RTSG protocol included a reduction of doxorubicin dosage from 50 to 30 mg/m^2 to avoid toxicity.[11] Funding was available to provide families with partial cover of out-of-pocket costs associated with treatment.

Implementation of the guideline was associated with improved end-of-treatment disease-free survival (68.5% vs. 52%, $p = .002$) and reduced treatment abandonment (12% vs. 23%, $p = .009$) compared to the pre-study baseline assessment.[13] The 2-year EFS was 49.9%.[14]

The Wilms Africa Phase II study used the same protocol, though described more comprehensively and available online.[15] For this study, more funding was available to provide data managers with dedicated time. The data collection tool was simplified including fewer data fields to facilitate complete data collection of surgical details.

The current Wilms Africa Phase II study (2021–2022) included 230 patients, among whom 164 had a nephrectomy. The aim of this study is to examine the surgical details and outcomes of these latter patients, including surgical operative report completion, percentage of completed surgical loco-regional spread assessment, tumour spillage, surgical complications and surgery-related mortality.

2 | METHODS

2.1 | Participating sites

Wilms Africa Phase II is a multicentre prospective clinical observational study involving collaboration between eight hospitals situated in six countries in Ghana (Accra and Kumasi), Malawi (Blantyre),

Zimbabwe (Harare), Ethiopia (Jimma and Gondar), Cameroon (Mbingo) and Uganda (Mbarara).

2.2 | Eligibility

Ethical approval was obtained from each institutional review board before patient enrolment commenced. Parent or guardian written consent for data collection was obtained after verbal explanation of the study. Eligibility criteria were the same as in Wilms Africa Phase I, and included first diagnosis of a unilateral WT (based on clinical examination and ultrasound) and age range between ≥6 months and less than 16 years.[13,14] Patients with a non-WT after histological verification were excluded from this analysis. Patient enrolment took place between 1 January 2021 and 31 December 2022.

2.3 | Diagnostic work-up and treatment

Diagnostic work-up and treatment were according to the adapted treatment Wilms Africa Phase II guideline published online.[15] Preoperative chemotherapy was recommended for all patients over 6 months of age. Children with localised tumours received a two-drug regimen (vincristine and actinomycin-D) for 4 weeks. Children with metastases evident on imaging at diagnosis received a 6-week, three-drug regimen (including doxorubicin). Postoperative chemotherapy was stratified by pathological stage and histological risk of the tumour (if available) according to the SIOP classification. If pathology results were not available in time, SIOP surgical stage was used.[15] Choice of postoperative chemotherapy regimen was at the local site lead's discretion. The Wilms Africa Phase II guideline described shorter (14 weeks) and longer (26 weeks) regimens using vincristine, actinomycin and doxorubicin.[15] Radiotherapy was inconsistently available in four sites (Ghana, Zimbabwe, Uganda).

2.4 | Surgical guidelines

The Wilms Africa modified surgical guidelines include the full SIOP surgical guidelines as a reference, follow these where possible and are summarised below.[15] General surgeons, urologists or paediatric surgeons may operate on a patient with a WT. It is important that a prescribed, formal operative protocol is followed. It is wise to avoid resection of adjacent organs. A report on the surgical staging, including difficulty of operation, abdominal metastases, sampled nodes and possible tumour spill or incomplete resection, is essential and will contribute to the determination of the intensity of postoperative chemotherapy. Delays in surgery are one of the known reasons of 'treatment abandonment' and are best avoided. If a delay is unavoidable, we recommend continuing preoperative chemotherapy with vincristine only in an attempt to achieve some tumour control without risking neutropenia at the time of surgery.

2.5 | Data collection

Patient data were collected on the study-specific case report form (CRF) prospectively filled in by clinicians and assimilated by local data managers for whom funding was provided. The CRF is included as an appendix. The following surgery-related details were collected: presence and site of any metastases; lymph nodes: normal, suspicious, or obviously infiltrated; lymph node resection done; tumour capsule rupture seen; procedure: biopsy only or total nephrectomy; complication during surgery; (partial) resection of other organs; tumour weight; largest tumour diameter; SIOP surgical stage: stage I: complete resection of an intrarenal tumour, stage 2: complete resection of an extrarenal tumour, stage 3: incomplete resection. Tumour weight and tumour largest diameter were also documented by the pathologist. Tumour weight and tumour largest diameter were analysed using the measurements at surgery and, if these were not available, the measurements done at pathology.

2.6 | Statistics

EFS time was calculated in days from diagnosis to date of last contact, either by clinic visit or active follow-up (phone or in-person). Survival was calculated both with treatment abandonment considered an event and patients with treatment abandonment censored. Treatment abandonment is defined as the interruption of treatment for at least 4 weeks for non-medical reasons.[16] Statistical analysis was performed using SPSS 22.0. Survival was calculated using a Kaplan–Meier curve. A chi-square test was used for categorical variables with Yates' correction applied to adjust for overestimation resulting from small sample size. A Spearman test was done to test correlation between continuous and categorical variables. A p-value less than .05 was considered statistically significant.

3 | RESULTS

We included 164 patients who went for surgery and were newly diagnosed with a WT between 1 January 2021 and 31 December 2022.

These 164 patients with a nephrectomy are 71% of the original cohort of 230 patients included into the Wilms Africa Phase II. The other 66 patients died before treatment (2), abandoned treatment before surgery (37), died during preoperative chemotherapy (19) or had persistent disease and were considered inoperable (due to persistent metastatic disease, too advanced disease or progressive disease). See Figure 1 for other details regarding the flow diagram of patient identification, enrolment and the events before, after and around nephrectomy.

The percentage of complete postoperative surgical case report template data was greater than 98%.

Median largest tumour diameter at diagnosis was 13.2 cm (range: 2–34 cm), and 30% (50/164) of patients had metastatic disease at diagnosis. For further details regarding patient and tumour characteristics of patients who had a nephrectomy, see Table 1.

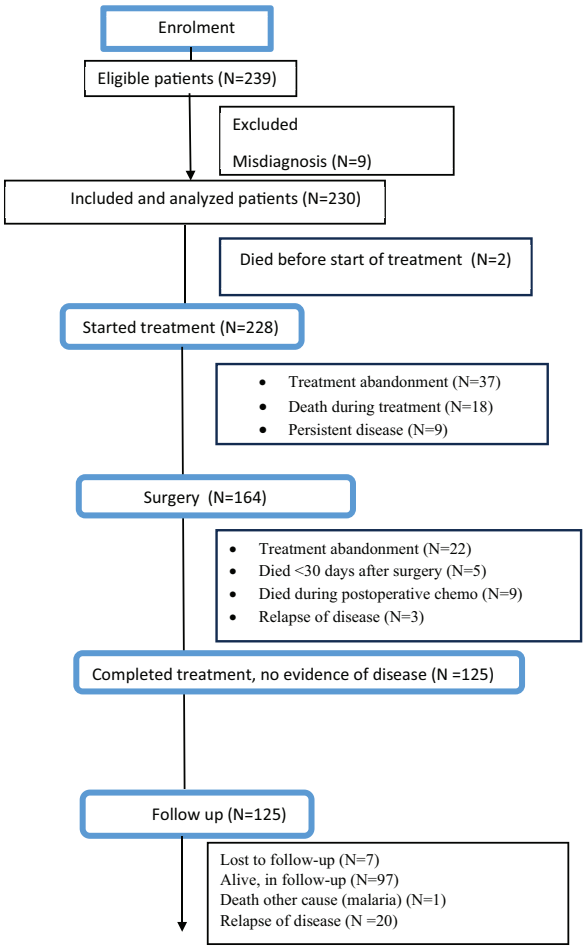

FIGURE 1 Flow diagram of patient identification, enrolment and the events before, after and around nephrectomy.

3.1 | Tumour weight and tumour diameter at surgery

Median tumour weight at surgery was 570 g (range: 204–5000 g). It was documented for 88% (149/164) of patients. Median tumour largest diameter was 11 cm (range: 2–38 cm). It was documented for 96% (157/164) of patients.

3.2 | Event-free survival

Two-year EFS after nephrectomy was 60.4% (±4.7%) with treatment abandonment as an event, and lower than the 72.6% (±4.7%) with treatment abandonment censored ($p = .03$) (Figure 2).

3.3 | Findings at surgery and performed procedures

Metastases were seen intraoperatively in 15% (24/164) of patients, and were documented to be in liver and lung ($n = 1$), liver ($n = 8$), lung ($n = 1$), lymph nodes ($n = 4$), abdominal wall, peritoneal, diaphragm ($n = 5$) and not specified ($n = 5$).

Out of the nine patients with liver metastases seen at surgery, four were already seen on the diagnostic ultrasound. Out of the two patients with lung metastases seen at surgery, both were already seen on the diagnostic chest x-ray.

Adjacent organ resection had to be performed on 11% (18/164) of patients. For further details regarding findings at surgery and the performed procedures, please see Table 2.

TABLE 1 Patient and tumour characteristics at diagnosis of the patients who had a nephrectomy ($N = 164$).

Patient characteristics	
Median age in years (range)	3.1 (0.5–13)
Female sex, *n* (%)	77 (47%)
Duration of symptoms >2 months, *n* (%)	59 (36%)
History of weight loss, *n* (%)	122 (74%)
Tumour characteristics	
Tumour side	
Tumour left side	83 (51%)
Tumour right side	81 (49%)
Localised or metastatic disease	
Localised	114 (70%)
Metastatic	50 (30%)
Site metastases	$N = 50$
Lung only	26 (52%)
Liver only	11 (22%)
Lung and liver	9 (18%)
Other[a]	4 (8%)[a]
Median tumour size in cm (range)	13.2 (2–34) ($N = 160$)

[a]Brain metastasis, peritoneum, not specified (2).

3.4 | Correlations of tumour weight and size with organ resection at surgery

Tumour weight at nephrectomy was not statistically significantly correlated with organ resection at surgery (correlation coefficient .12, $p < .07$). Tumour diameter at nephrectomy was not statistically significantly correlated with organ resection at surgery (Spearman's rho, correlation coefficient .02, $p = .2$).

3.5 | Lymph node involvement, including pathologist's reporting

Lymph node sampling was completed for 74.3% of patients (122/164) as reported by the surgeon. The pathologist reported on the lymph nodes of 74.6% (91/122) of patients in whom these were sampled.

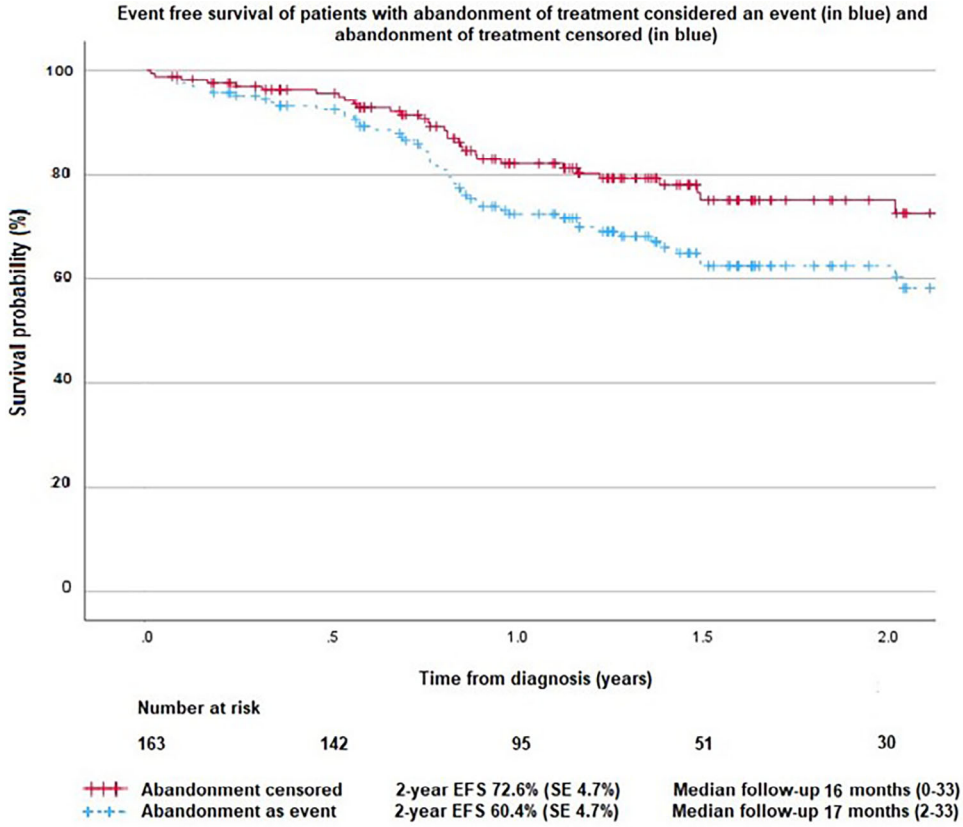

FIGURE 2 Kaplan–Meier analysis of the 164 patients who had a nephrectomy; treatment abandonment considered an event (in blue), and treatment abandonment censored (in red).

TABLE 2 Findings at surgery and performed procedures ($N = 164$).

Characteristic	*n* (%)
Did you see metastases	
Yes	24 (15%)
No	139 (85%)
Missing	1 (0.6%)
Appearance of lymph nodes	
Normal	80 (49%)
Suspicious	66 (40%)
Obviously infiltrated	17 (10%)
Missing	1 (0.6%)
Lymph nodes resected	
Yes	122 (74%)
No	41 (25%)
Missing	1 (0.6%)
Surgery type	
Biopsy	0 (0%)
Total nephrectomy	164 (100%)
Organ resection	
Yes	18 (11%)
No	146 (89%)

TABLE 3 Documented complications during surgery ($N = 164$).

Characteristics	*n* (%)
Tumour spillage/rupture	34 (21%)
Bleeding	4 (2%)
IVC laceration	5 (3%)

Abbreviation: IVC, inferior vena cava.

3.6 | Tumour rupture and correlation with tumour size and weight

Tumour spillage or rupture was documented in 21% (34/164) of patients. Both maximum tumour diameter and tumour weight were significantly correlated with a tumour rupture seen at surgery; Spearman's rho, correlation coefficient, respectively, .3, $p < .01$ for tumour diameter and .18, $p < .02$ for tumour weight. See Table 3 for details on complications during surgery.

3.7 | Surgery-related mortality

Documented surgery-related mortality was 3% (5/164). Four patients died at the day of surgery, all due to bleeding. One patient died 2 days

TABLE 4 Documented surgical stage ($N = 164$).

Characteristic	*n* (%)
Surgical stage	
Stage I: Completely resected intrarenal tumour	57 (35%)
Stage II: Completely resected extrarenal tumour	82 (50%)
Stage III: Incompletely resected tumour	25 (15%)

after surgery, possibly due to an infection. No other patients died within 30 days of surgery.

3.8 | Relapse of disease and increased risk of relapse with tumour rupture

Fourteen percent of patients (23/164) had a relapse of disease after a median follow-up of 17 (range: 2–33) months. Eight of these were either in the renal bed or abdominal without further specification, and for a further 15 the site was not specified.

Relapse of disease was more frequent in patients with a tumour rupture than in those who did not have a tumour rupture; 26.5% (9/34) versus 10.8% (14/130) ($p < .04$).

3.9 | Surgical stage

Documentation of surgical stage was done inconsistently. Of patients with a documented surgical stage I or II, 12.9% (18/139) also had a tumour rupture and should have been documented as surgical stage III. With this correction, 22% of patients (39) had stage I, 50% had stage II and 28% (43) had stage III. See Table 4 for the surgical stage as it was documented.

4 | DISCUSSION

This study reports the surgical aspects and outcomes of a multicentre, prospective clinical trial in sub-Sharan Africa, using a consensus Wilms Africa comprehensive treatment guideline adapted to local circumstances and a specific synoptic surgical CRF.

It is, to our knowledge, the first study in sub-Saharan Africa or a similarly resourced setting documenting this level of detail of local evidence of WT surgical findings, procedures and outcome. This makes it difficult to compare with reports from similar settings. It may serve as a baseline for future studies on WT surgery in our region.

The team achieved 98% complete data. This is a significant achievement appreciating the barriers for such a resource-limited setting with many other priorities than collecting data. Facilitators included the use of the synoptic form with limited data fields, the fact that the multidisciplinary Wilms Africa teams have successfully collaborated for many years and the funding for dedicated time of data managers. A similar template for operative reporting of paediatric cancer surgery in limited resource settings has been developed by a modified Delphi method.[17]

Adequate lymph node sampling is essential for optimal staging and was done for 74.3% of patients. This compares quite well to a 9% non-sampling rate in a study in North America and 33% in Germany.[18,19] The utilisation of a prospectively filled synoptic operative report may have facilitated this documentation. Unfortunately, though, only 75% of the patients with lymph node sampling were reported upon by the pathologist. The reasons for this are unknown. Regular multidisciplinary meetings are key to improve collaborations between surgeons and pathologists and may help to further improve lymph node sampling and also examination rates by the pathologists.

Tumours in our study were still large at surgery after preoperative chemotherapy, with a median size of 11 cm (range: 2–38 cm) and median weight of 570 g (range: 204–5000 g). Tumour size before nephrectomy has not been documented in other WT studies from sub-Saharan Africa, and is often reported as a volume (requiring three dimensions) from HICs, which makes it difficult to compare. Still, the fact that mean tumour volume at diagnosis in the SIOP 9 study was 470 m, corresponding to a tumour diameter of 9–10 cm illustrates how much larger the tumours are in our setting and study.[20]

In our opinion, late presentation with advanced disease (in our study median tumour size of 13.2 cm at diagnosis) is the main reason for these large tumours. Another reason may be that the preoperative chemotherapy is less efficacious than in other settings, either due to the reduced dosage of doxorubicin in our study or because of tumour characteristics.[11]

We confirmed in our study the expectation and experience on the ground that large tumour size at nephrectomy is correlated with the risk of tumour rupture. The proportion of patients with a tumour rupture was 20.7%, and tumour rupture was significantly correlated to tumour size ($p < .01$) and tumour weight ($p < .02$). This 20.7% tumour rupture was much higher than the 3% in a SIOP study after preoperative chemotherapy, and similar to a study in Malawi (20%) and a study in Durban, South Africa (21%) among a selected group of patients with tumours exceeding 1000 g at surgery.[20–22] Reported tumour rupture rate was 12% in patients with localised disease in a GFAOP study in sub-Saharan Africa, but authors state that this could not be confirmed due to absence and non-concordance of written surgical and histological reports.[23] Earlier presentation is expected to decrease the proportion of patients with a tumour rupture. Prolonged and/or intensified preoperative chemotherapy may need to be considered for patients with large and localised tumours.

En bloc resection of other organs with tumour resection is generally avoided. In our study, it was necessary in 18 patients (10.9%). The need for this was almost statistically significantly correlated with tumour weight ($p < .07$), but not with tumour size ($p = .2$). En bloc resection of other organs is rare in high-income countries).

Two-year EFS post nephrectomy was 60.4% ± 4.7% with treatment abandonment considered an event and lower than 72.6% ± 4.7% ($p = .03$) with treatment abandonment censored. Post-nephrectomy survival was challenged by treatment abandonment (13%), death during postoperative chemotherapy (8.5%) and relapse of disease (14%).

Three-year OS post nephrectomy was 76.1% in Rwanda and 69% in a multicentre study in French-speaking sub-Saharan Africa (after exclusion of patients with unfavourable pathology and metastatic disease).[23,24]

Relapse of disease was 14% (23/164, median follow-up 20 months), and although in the majority (15) the site of relapse was not indicated, a significant proportion (at least eight) of the relapses were local relapses in the abdomen. Not surprisingly, the proportion of patients with a relapse of disease was higher in patients with a tumour rupture (26.5% vs. 10.8%, $p < .04$), as also reported in other studies.[19] These results suggest that both earlier presentation, leading to smaller tumour size at surgery, and less tumour ruptures and the access to radiotherapy would be expected to lead to reduced relapse of disease. It may also need to be considered to intensify and/or prolong preoperative chemotherapy for patients with larger localised tumours.

Documented surgery-related mortality was only 3%, and was caused by bleeding in all five patients. There was no separate documentation of surgery-related mortality within the 30 days after the operation on the CRF, though this may have led to underreporting of deaths in that specific postsurgical period.

The strength of this study is in the prospective documentation, the use of a synoptic operative reporting form and the high percentage of completion of data achieved in very low-resourced settings in sub-Saharan Africa. Data rigorously collected in low-income countries is key to understanding the local situation and to be able to consider interventions that might impact the improvement of care and so increase survival.

There are several weaknesses of the study. Surgery-related mortality within 30 days of surgery was not separately documented, which may have led to underreporting. Surgical complications other than tumour rupture were not specifically mentioned in the CRF and probably underreported. The surgical staging was not always consistent with the protocol. Pathology staging and risk classification results were too inconsistent with the protocol to be included in this study and will be audited separately.

In conclusion, patients present late and with advanced disease. Large tumours after preoperative chemotherapy are associated with a higher risk of tumour rupture. Survival after nephrectomy is challenged by treatment abandonment, treatment-related mortality and a higher risk of relapse associated with larger tumours at presentation. Early diagnosis and access to radiotherapy are expected to improve survival. More intense or longer preoperative chemotherapy may be considered for patients with localised disease and large tumours.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

Data available on request from the authors.

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