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Original Article

Long-term outcome after surgical resection of non-high-risk gastrointestinal stromal tumours without adjuvant therapy

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Abstract

Background: Gastrointestinal stromal tumour (GIST) is the most common intra-abdominal sarcoma. Risk classification systems, commonly the modified National Institutes of Health consensus criteria, identify tumour properties relating to patient outcomes. However, owing to limited long-term evidence, most guidelines recommend up to 10-year follow-up for all risk groups except very low-risk GIST.

Methods: This retrospective multicentre study included patients who had complete resection of primary, non-metastatic GIST from three Scandinavian sarcoma centres: Gothenburg (2004–2020), Stockholm (2000–2019), and Oslo (2000–2017). Medical records were reviewed for clinical details regarding diagnosis, treatment, and follow-up, and recurrence-free and disease-specific survival evaluated.

Results: The total cohort consisted of 1213 patients with GIST. High-risk patients and those treated with tyrosine kinase inhibitors were excluded. The remaining 649 patients were included in the present analysis: 118 with very low-, 381 with low-, and 150 with intermediate-risk GISTs. Five-year recurrence-free survival rates were 100, 98.5, and 100 per cent for the intermediate-, low-, and very low-risk groups respectively ($P = 0.246$). Disease-specific survival rates 10 years after surgery were 100, 98.4, and 100 per cent for the intermediate-, low-, and very low-risk groups respectively ($P = 0.262$).

Conclusion: Patients with completely resected non-high-risk GISTs have an excellent long-term outcome, irrespective of risk group. Follow-up programmes to detect disease recurrences in these patients are probably not indicated.

Introduction

Gastrointestinal stromal tumour (GIST) was recognized as a unique and heterogenous sarcoma in the late 20th century[1,2]. The tumours vary from small with an indolent nature to aggressive tumours with poor prognosis[3]. The modified National Institute of Health (NIH) consensus criteria are often used to estimate the risk of recurrence, and patients are categorized into four risk groups (very low, low, intermediate, and high risk) according to tumour size, mitotic rate, tumour rupture, and anatomical location[4,5]. The Armed Forces Institute of Pathology (AFIP)[3,6] criteria are also well established, and other prognostic contour maps have been proposed[7]. An important aim of these classification systems is to identify patients at high risk of recurrence who may benefit from adjuvant treatment with the tyrosine kinase inhibitor (TKI) imatinib. RCTs[8–10] have shown improved survival with adjuvant imatinib but only for patients with a high risk of recurrence; patients with a (very) low to intermediate risk of recurrence were often excluded from these studies. Hence, the need for, and duration of, follow-up in the remaining risk-groups is not well defined[11].

The National Comprehensive Cancer Network[12] and European Society for Medical Oncology[13] guidelines indicate that there is

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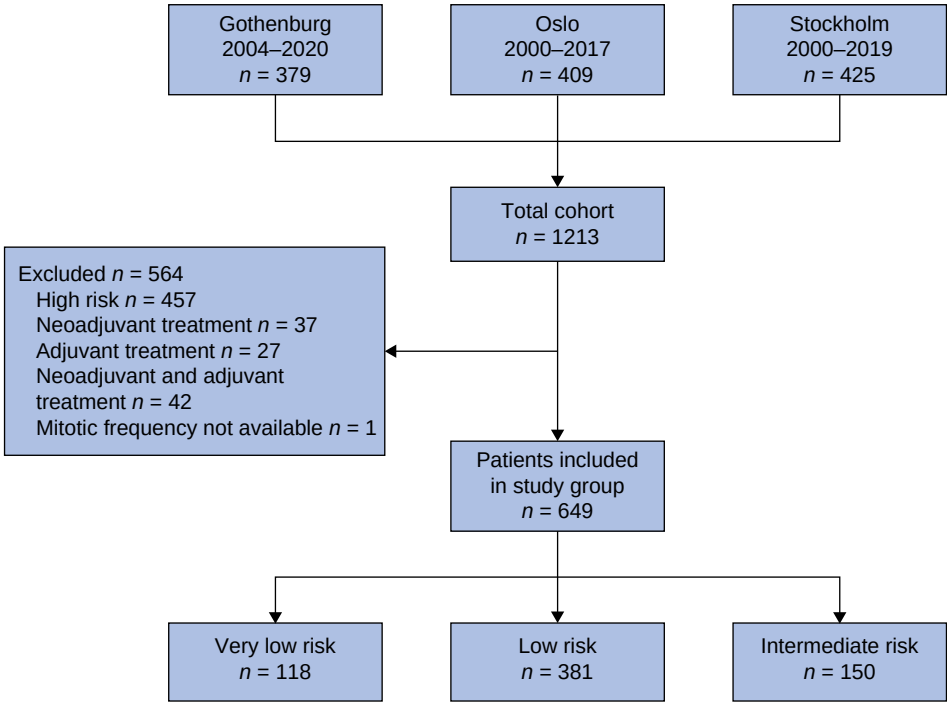


Fig. 1 Flow chart for the study

paucity of data on the best follow-up approach for non-high-risk GIST after resection. As no established biomarkers for GIST are available, detecting recurrence is based on repeated cross-sectional imaging with CT or MRI. Follow-up differs widely across institutions although most agree on 10 years for high-risk GIST. In the lower-risk groups, the benefit of repeated CT is unclear, and unnecessary repeated exposure to radiation should be avoided[14]. Therefore, this study aimed to assess survival in a large cohort of patients who underwent surgical resection for a non-high-risk GIST.

Methods

Patients

This retrospective study included three cohorts of patients who were diagnosed with a primary, non-metastatic GIST that underwent complete tumour resection. Patients who received treatment with either neoadjuvant or adjuvant TKI were excluded.

Patient data were retrieved from three institutions in Gothenburg (January 2004 to December 2020), Oslo (January 2000 to September 2017), and Stockholm (January 2000 to December 2019). Patient and tumour characteristics, radiological findings, surgical outcomes, and recurrences were collected from the medical records for the Gothenburg and Stockholm cohorts. Data for the Oslo cohort were retrieved from a prospective database and supplemented by review of medical records[15].

The surgical margin was assessed from the resection specimen and classified as R0 (tumour-free margin), R1 (microscopic tumour at the resection margin) or R2 (macroscopic tumour left behind) according to the TNM classification[16]. The tumour size was measured on the surgical specimen after fixation in formalin. The mitotic count was first estimated as the rate per 50 high-power fields, but later changed to the rate per 5 mm^2, reflecting changes in the WHO classification guidelines from 2020[17].

The study was approved by the Swedish Ethical Review Authority in May 2022 (2022-02827-02), the Stockholm Regional Ethics Committee in September 2020 (2020-04892), and by the Data Protection Officer at Oslo University Hospital in April 2018 (18/05487).

Risk stratification and follow-up

Risk stratification was performed according to the modified consensus criteria from the NIH (*Table S1*) and the AFIP (*Table S2*).

Date of last follow-up was registered as date of last imaging (Gothenburg and Oslo cohorts) or last hospital visit (Stockholm cohort). Recurrence was recorded as locoregional (local peritoneal recurrence), visceral (metastatic disease) or concurrent (both local peritoneal recurrence and metastatic disease). Recurrence-free survival (RFS) was defined as the interval from surgery to recurrence (local and/or distant), and patients without recurrence were censored at the latest date of follow-up. Disease-specific survival (DSS) was calculated from the date of diagnosis to the date of death from GIST. Patients were censored at the date of latest follow-up (December 2021 for the Gothenburg cohort, January 2023 for the Oslo cohort, and May 2020 for the Stockholm cohort) or date of death (non-GIST-related).

Follow-up protocols varied between patients and with time for the three cohorts. The Swedish national medical guidelines for abdominal sarcomas[18], adopted in 2018, recommend imaging every 6 months for 5 years, and annually for up to 10 years, excluding patients with very low risk of recurrence. The Norwegian national medical guidelines for abdominal sarcomas[19] do not recommend any follow-up for patients other than the high-risk group.

Table 1 Patient and tumour characteristics and risk classification according to centre

	Gothenburg ($n = 165$)	Oslo ($n = 247$)	Stockholm ($n = 237$)	Total ($n = 649$)
Age (years), median (i.q.r.)	68.5 (61–75)	66 (58–73)	68.7 (59–75)	67 (59–74)
Sex ratio (M : F)	84 : 81	124 : 123	103 : 134	311 : 338
Tumour location				
Oesophagus	0 (0)	1 (0.5)	0 (0)	1 (0.1)
Stomach	132 (80)	201 (81.5)	191 (80.5)	524 (81)
Small intestine	29 (17.5)	38 (15.5)	45 (19)	112 (17)
Colorectal	4 (2.5)	7 (2.5)	1 (0.5)	12 (2)
Tumour size (cm), median (i.q.r.)	3.0 (1.7–4)	3.5 (2.6–5)	3.5 (2.4–4.5)	3.3 (2.3–4.5)
Mitoses per 5 mm^2, median (i.q.r.)	2 (1–4)	2 (1–3)	2 (1–4)	2 (1–4)
Modified NIH risk criteria				
Very low	47 (28)	35 (14)	36 (15)	118 (18)
Low	83 (50)	144 (58)	154 (65)	381 (59)
Intermediate	35 (22)	68 (28)	47 (20)	150 (23)
AFIP grade				
1	47 (28.5)	35 (14)	36 (15)	118 (18)
2	86 (52)	144 (58)	155 (65.5)	385 (59)
3a	17 (10.5)	58 (23)	35 (15)	110 (17)
4	3 (2)	1 (0.5)	2 (1)	6 (1)
5	12 (7)	9 (3.5)	9 (3.5)	30 (5)
Mutation analysis	110 (67)	184 (74)	150 (63)	445 (68)
Kit exon 11	64 (39)	122 (49)	88 (37)	274 (42)
Other *Kit* exons	9 (5.5)	7 (3)	8 (3.5)	24 (4)
PDGFRA	28 (17)	41 (16.5)	14 (6)	83 (13)
No mutation detected	17 (10)	14 (5.5)	40 (17)	71 (11)
Resection margin				
R0	151 (91.5)	223 (90)	225 (95)	600 (92)
R1	13 (8)	24 (10)	10 (4)	47 (7)

Values are *n* (%) unless otherwise indicated. NIH, National Institutes of Health; AFIP, Armed Forces Institute of Pathology; PDGFRA, platelet-derived growth factor α.

Statistical analysis

Continuous variables are presented as median (range), and categorical variables as numbers with percentages. The primary outcomes, RFS and DSS for patients with very low-, low-, and intermediate-risk GIST, were estimated using the Kaplan–Meier method and compared between groups using the log rank test. The number needed to follow up to detect 1 disease recurrence was calculated as 1 divided by the difference between 100 per cent RFS and the estimated RFS: 1/(100 per cent – RFS). $P < 0.050$ was considered statistically significant. Data analysis was performed using R version 4.1.2 (R Foundation for Statistical Computing, Vienna, Austria) and R Studio® (Posit™, PBC, Boston, Massachusetts).

Results

Patients

In total, 1213 patients were identified, of whom 564 were excluded as they had received neoadjuvant or adjuvant TKI treatment or had a high-risk GIST (*Fig. 1*). Patient and tumour characteristics for the remaining 649 patients are summarized in *Table 1*. There were 118 very low-, 381 low-, and 150 intermediate-risk GISTs according to the modified NIH consensus criteria. The very low-risk and low-risk groups according to NIH criteria corresponded to risk groups 1 and 2 according to AFIP criteria respectively. However, the intermediate-risk group based on NIH criteria was divided into three risk groups according to AFIP criteria: 3a, 4, and 5.

Recurrence-free and disease-specific survival

Median follow-up for the total cohort was 50.5 (i.q.r. 19.2–74.5) months. It was 58.6 (31.3–81.6) months in the intermediate-risk group, 52.7 (20.1–75.0) months in the low-risk group, and 23.2 (2.8–61.7) months in the very low-risk group.

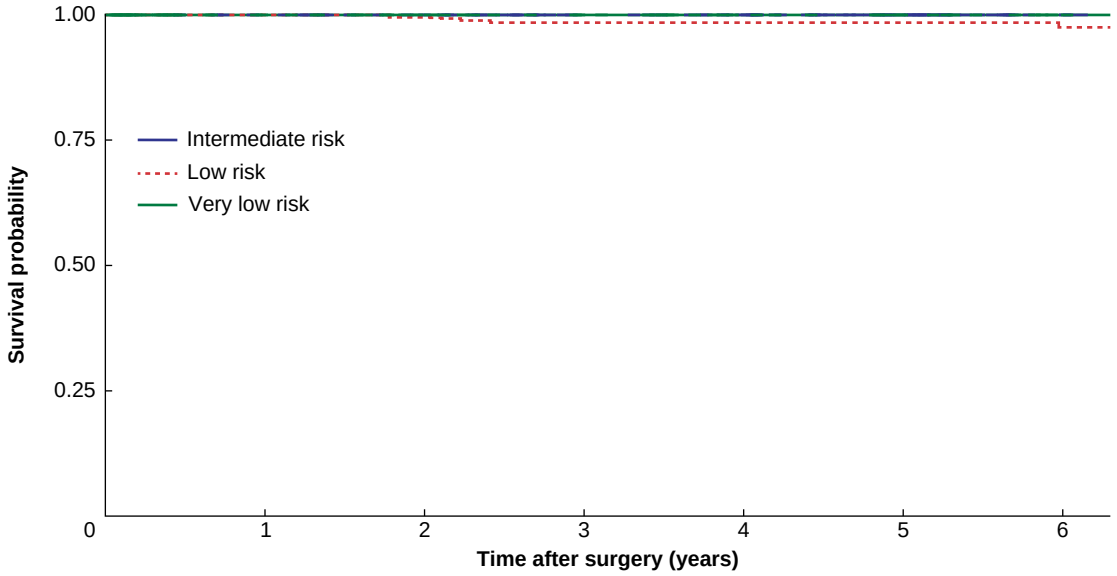
Table 2 Details of eight patients with recurrent disease

	Recurrences ($n = 8$)
Age (years), median (i.q.r)	59 (53–67)
Sex ratio (M : F)	5 : 3
Tumour location	
Stomach	3 (38)
Other	5 (62)
NIH risk score	
Very low	0
Low	7* (87)
Intermediate	1† (13)
Mutation analysis	
Kit exon 11	4 (50)
Other	4 (50)
Radical resection, R0	8 (100)
Recurrence site	
Locoregional	2 (25)
Visceral	4 (50)
Concurrent	2 (25)
RFS (months), median (i.q.r.)	50.5 (2.8–61.7)
Death from GIST	4 (50)

Values are n (%) unless otherwise indicated. *Four non-gastric tumours with diameter between 4 and 5 cm; †9-cm gastric tumour. NIH, National Institutes of Health; RFS, recurrence-free survival; GIST, gastrointestinal stromal tumour.

Only eight patients (1.2 per cent) were diagnosed with recurrent disease (*Table 2*). The number needed to be followed up to discover a relapse was therefore 83 patients. The median mitotic frequency of the recurrent tumours was 1 (i.q.r. 1–2.3) mitoses per 5 mm^2. The recurrence in the intermediate-risk group was from a tumour in the AFIP 3a risk group and occurred 10.4 years after surgical resection.

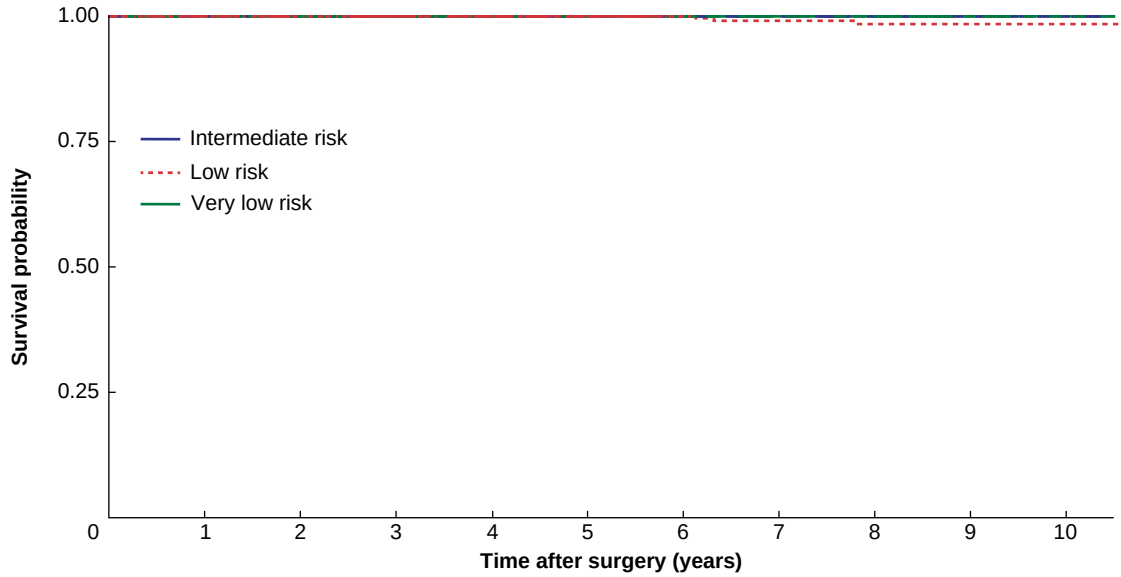
Median RFS for the patients with recurrent disease was 50.5 (i.q.r. 2.8–61.7) months (*Fig. S1*). *Figure 2* show RFS for patients in the non-high-risk groups. The 5-year RFS rate was 99.1 per cent for the total cohort, and 100, 98.5, and 100 per cent for the intermediate-, low-, and very low-risk groups respectively.



No. at risk

Intermediate risk	150	139	126	107	98	71	47
Low risk	381	313	280	236	204	154	103
Very low risk	118	72	58	49	39	30	22

Fig. 2 Kaplan–Meier curves illustrating recurrence-free survival according to risk groups (modified National Institutes of Health consensus criteria)
$P = 0.246$ (log rank test).



No. at risk

Intermediate risk	150	141	135	120	109	97	81	71	62	50	41
Low risk	381	360	341	312	286	256	210	179	152	123	99
Very low risk	118	109	100	88	70	59	54	45	41	25	19

Fig. 3 Kaplan–Meier curves illustrating disease-specific survival after resection of a non-high-risk gastrointestinal stromal tumour according to the modified National Institutes of Health consensus criteria
$P = 0.262$ (log rank test).

The corresponding 10-year RFS rates were 96.4 per cent overall, and 100, 93.8, and 100 per cent in the intermediate-, low-, and very low-risk groups respectively.

According to AFIP criteria, the 5-year RFS rate was 98.5 per cent for risk group 2 and 100 per cent for the remaining risk groups. The 10-year RFS rate was 93.8 per cent for risk group 2 and 100 per cent for the remaining risk groups; the difference was not statistically significant ($P = 0.603$) (*Fig. S2*). There was no significant difference in RFS between the different centres ($P = 0.961$) (*Fig. S3*).

DSS rates at 10 years were 99 per cent overall, and 100, 98.4, and 100 per cent for the intermediate-, low-, and very low-risk groups respectively (*Fig. 3*). Based on AFIP criteria, the 10-year DSS rate was 98.4 per cent for risk group 2 and 100 per cent for the remaining risk groups, with no statistically significant difference between risk groups ($P = 0.618$) (*Fig. S4*).

Discussion

In this study, GISTs classified as non-high risk had an excellent long-term outcome after surgical resection without adjuvant therapy. The 5-year RFS rate was 99.1 per cent and the 10-year DSS rate 99 per cent. There was no difference in long-term survival between the intermediate-, low-, and very low-risk groups. Hence, this study suggests that routine follow-up to detect disease recurrence is not beneficial for patients with a non-high-risk GIST.

The modified NIH consensus criteria were previously validated by Joensuu *et al.*[7], who analysed several retrospective population-based cohorts before the use of TKIs. The analysis compared the original and modified NIH consensus criteria, and the AFIP criteria. The difference between the original NIH consensus criteria and the modified version is that small (5 cm or smaller) non-gastric GISTs with more than 5 mitoses per 5 mm^2, as well as non-gastric tumours, 5–10 cm in size with fewer than 5 mitoses per 5 mm^2, were moved from the intermediate- to the high-risk group. Ruptured GISTs were also considered high-risk tumours, irrespective of other features. The RFS rates in risk groups defined according to different risk criteria were compared, and the analysis demonstrated that the modified NIH criteria were superior for identifying a high-risk group that could benefit from treatment with TKIs. In line with the present study, the three non-high-risk groups had similar RFS when stratified according to the modified NIH consensus criteria. Based on these findings, the very low-, low-, and intermediate-risk groups could be merged into a single low-risk group. This would simplify clinical practice, provide a more correct nomenclature, and also allow separation of the high-risk group into intermediate- and high-risk subgroups, if additional prognostic factors were identified within the high-risk group.

The optimal follow-up schedule for surgically resected GIST needs clarification[13] and, as the present analysis has demonstrated, the time to recurrence can vary from a few months to over 10 years. European guidelines suggest no follow-up for the very low-risk group. However, the routine follow-up of intermediate- and low-risk groups varies among centres[12,13]. In Norway, follow-up is selective, whereas the Swedish guidelines suggest abdominal CT every 6 months for 5 years and annually for another 5 years[18,19]. Assuming that the patient's tumour can be risk-stratified easily and does not require neoadjuvant or adjuvant imatinib treatment, it is appropriate not to undertake postoperative CT in non-high-risk patients. The strategy may be modified on an individual basis, when a tumour is borderline for size and/or mitotic frequency and resembles a high-risk lesion.

In the present study, the recurrence rate for the intermediate- and low-risk groups was only 1.2 per cent. The number of patients needed to follow up to detect a recurrence was 83. In a follow-up programme similar to the one in Sweden, this translates into over 1000 CT scans needed to detect a single recurrence. A study[20] investigating fear of cancer recurrence and quality of life in patients with GIST found no correlation between fear of cancer recurrence and disease status. Patients with metastatic disease experienced the same level of fear as those who had undergone surgery with curative intent. Therefore, the follow-up schedule could potentially induce fear of cancer recurrence. The authors also defined 'scanxiety', which refers to the anxiety accompanying imaging in cancer follow-up. Its presence appears to be associated with reduced quality of life[21]. A recent study[22] evaluating health-related quality of life during oncological follow-up after surgery found that less intensive surveillance does not diminish emotional well-being or patient satisfaction. Taken together, the disadvantages of routine follow-up for detecting disease recurrence in patients with a non-high-risk GIST may outweigh the potential benefit.

The strengths of this study are that it comprised analysis of a large cohort with long-term follow-up from three Scandinavian tertiary referral centres. The Scandinavian healthcare system based on patient's personal identity number and the centralization of sarcoma care makes it unlikely that late recurrences in this cohort would have been missed when follow-up was discontinued. The cohorts from the three centres are equivalent, with similar patient characteristics and outcomes. The limitations of this study are that it is retrospective in nature, and patients who had been treated with TKIs had to be excluded. Most excluded patients were from the Gothenburg cohort. In Gothenburg, the alternative GIST Risk Score (GRS) was used during part of the study interval[23]. This score is based on tumour size and proliferation index (Ki-67 per cent). When the GRS was used, more non-high-risk patients received neoadjuvant treatment. Risk stratification after treatment with TKIs becomes unreliable owing to changes in size and mitotic frequencies[24]. It is therefore essential that neoadjuvant treatment is used only for patients with locally advanced tumours and when upfront surgery is not feasible owing to high risk of morbidity[12,13].

This study has shown that patients with primary resected non-metastatic GISTs in the intermediate-, low-, and very low-risk groups have excellent and equivalent long-term RFS and DSS rates. Therefore, these risk groups should be merged into a single low-risk category. The low rate of recurrence after surgical treatment for low- and intermediate-risk GISTs suggests that postoperative surveillance may not be needed.

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Author contributions

Marta Berndsen (Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Software, Visualization,

Writing—original draft, Writing—review & editing), Sara Renberg (Data curation, Investigation, Writing—review & editing), Toto Hølmebakk (Data curation, Investigation, Writing—review & editing), Emma Hancke (Data curation, Investigation, Writing—review & editing), Florian Puls (Resources, Validation, Writing—review & editing), Fredrik Karlsson (Data curation, Investigation, Writing—review & editing), Stephan Stoldt (Data curation, Investigation, Writing—review & editing), Bodil Bjerkehagen (Resources, Validation, Writing—review & editing), Felix Haglund de Flon (Resources, Validation, Writing—review & editing), Andreas Muth (Conceptualization, Methodology, Supervision, Visualization, Project administration, Resources, Writing—review & editing), Andri Papakonstantinou (Conceptualization, Methodology, Supervision, Visualization, Project administration, Resources, Writing—review & editing), Kjetil Boye (Conceptualization, Methodology, Supervision, Visualization, Project administration, Resources, Writing—review & editing), and Stefan Lindskog (Conceptualization, Methodology, Supervision, Visualization, Project administration, Resources, Writing—original draft, Writing—review & editing).

Disclosure

The authors declare no conflict of interest.

Supplementary material

Supplementary material is available at *BJS* online.

Data availability

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available owing to privacy restrictions.

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Michel Adamina, Winterthur, CH

Metastatic Colorectal Cancer – surgical approaches and limits
Jürgen Weitz, Dresden, DE

Extended lymph node dissection for rectal cancer, is it still under debate?
Miranda Kusters, Amsterdam, NL

Organ preservation functional outcome in rectal cancer treatment – in line with patient's needs? (Robot – laparoscopic – open surgery?)
Hans de Wilt, Nijmegen, NL

ROBOTICS

Advances in Robotic Surgery and what we learnt so far
Parvaiz Amjad, Portsmouth, UK

Challenging the market: Robotic (assistant) Devices and how to choose wisely (Da Vinci – Hugo Ras – Distalmotion ua)
Khan Jim, London, UK

TAMIS - Robotic Transanal Surgery, does it make it easier?
Knol Joep, Genk, BE

Live Surgery – Contonal Hospital of St.Gallen
Walter Brunner, St.Gallen, CH;
Salvadore Conde Morals, Sevilla, ES;
Friedrich Herbst, Vienna, AUT;
Amjad Parvaiz, Portsmouth, UK

Video Session

Lars Pahlmann Lecture
Markus Büchler, Lisboa, PRT

Honorary Lecture
Bill Heald, Lisboa, PRT

Information & Registration **www.colorectalsurgery.eu**