

EORTC 1409 GITCG / ESSO 01: Primary analysis of A prospective colorectal liver metastasis database with an integrated quality assurance program (CLIMB)

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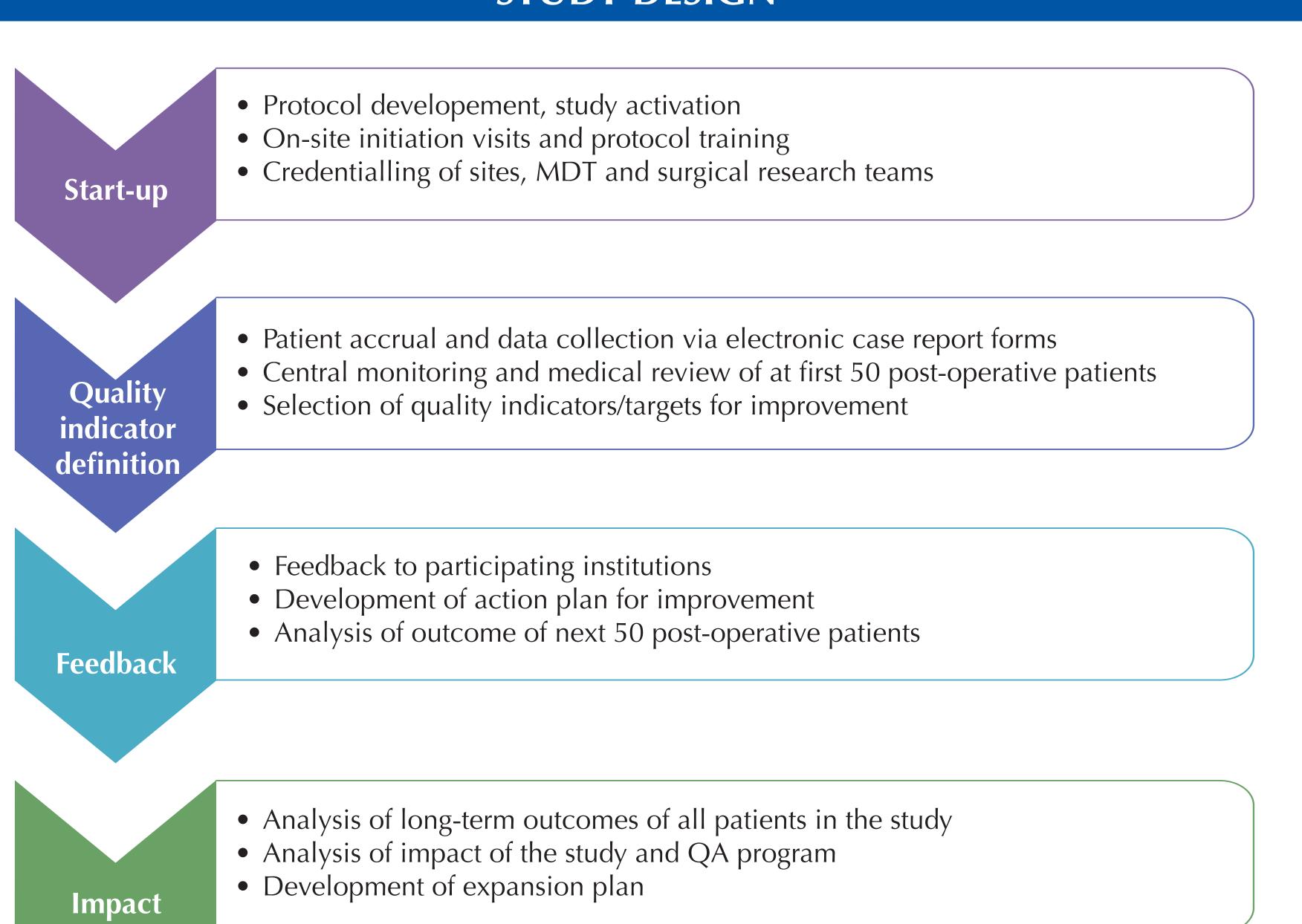
CONCEPT OVERVIEW

The European Organization for Research & Treatment of Cancer & European Society of Surgical Oncology joined forces to build an infrastructure for surgical quality assurance (QA) in clinical trials (SURCARE) and advance the surgical research agenda in Europe. Benchmarking is a critical step to achieve this. Their first project is CLIMB, a prospective study to evaluate complications and identify indicators for improvement in surgery for unresectable or borderline resectable colorectal liver metastasis (CRLM).

METHODS

CLIMB (NCT02218801) opened in 2015 in 9 countries and 14 specialised centers for liver surgery. Eligible patients were registered after multidisciplinary evaluation and before surgery. Primary endpoint was 30 and 90 day surgical complication rate. On-site visits and central review ensured prospective data inclusion of the following: biomarker, imaging, chemotherapy, surgery, complications graded by Clavien-Dindo classification and survival. Data until post op day 90 were analysed but long term outcome will be reported after all patients were followed for two years after registration.

STUDY DESIGN



CONCLUSION

CLIMB prospectively collected data from complex surgery for unresectable CRLM. Two stage surgery had more grade≥3 complications. Harmonizing standards in multidisciplinary evaluation, biomarker testing and imaging may improve this outcome. SURCARE will use these indicators to develop trials with enhanced QA methods to improve cancer surgery.

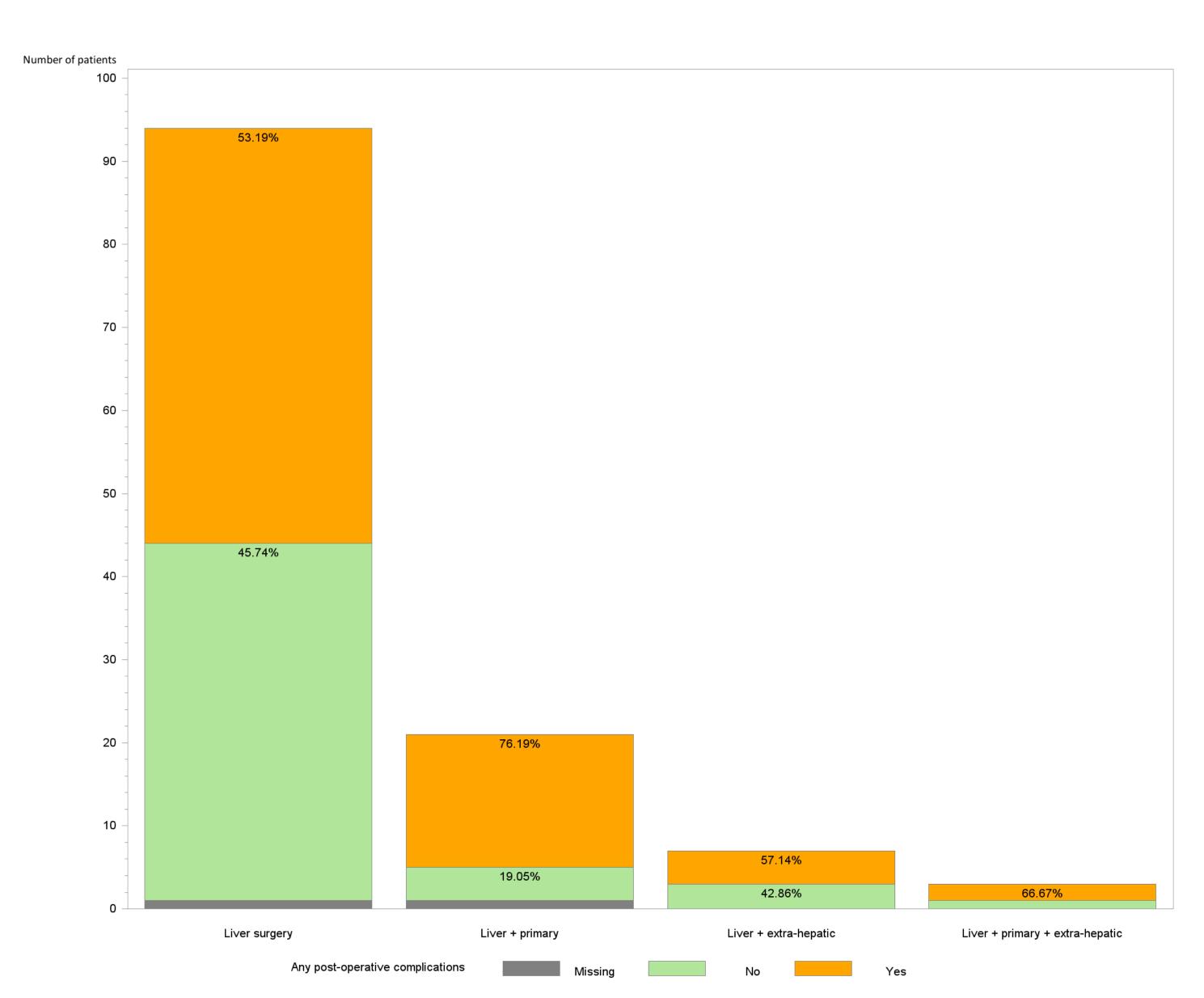
Among 210 patients registered, 126 (60%) who had at least one liver surgery were analysed. 73% had left-sided or rectal primary tumor, 95.2% had synchronous primary and liver metastasis, 19.8% had extra-hepatic lesions and CRLM. Most patients (N = 95, 75.4%) had one stage liver surgery while 30 (23.8%) had two stage liver surgery, 10 of whom had ALPSS. Over-all complication rates for one stage was 53.7% (95% CI [43%, 64%]), 17.9% (95% CI [11%, 27%]) with grade≥3 and 93.3% (95% CI [78%, 99%]) for two stage, 46.7% (95% CI [28%, 66%]) with grade≥3 including two deaths. Intra-abdominal, wound and urinary tract infections, bile leak and post hepatectomy liver failure grade A were most commonly reported over-all.

	BASELINE PATIENT CHARACTERISTICS IN CLIMB			
		Patients used in analysis (N=126) N (%)		
Age at registration (in years)	<=55 years	42 (33.3)		
	56 - 65 years	45 (35.7)		
	66 - 75 years	31 (24.6)		
	>75 years	8 (6.3)		
Sex	Male	81 (64.3)		
	Female	45 (35.7)		
WHO Performance Status	0	89 (70.6)		
	1	31 (24.6)		
	2	2 (1.6)		
	3	1 (0.8)		
	Unknown	3 (2.4)		
Presence of significant comorbidities	None	79 (62.7)		
	Diabetes Mellitus	7 (5.6)		
	Cardiovascular	8 (6.3)		
	Respiratory	2 (1.6)		
	Multiple	20 (15.9)		
	Other	10 (7.9)		

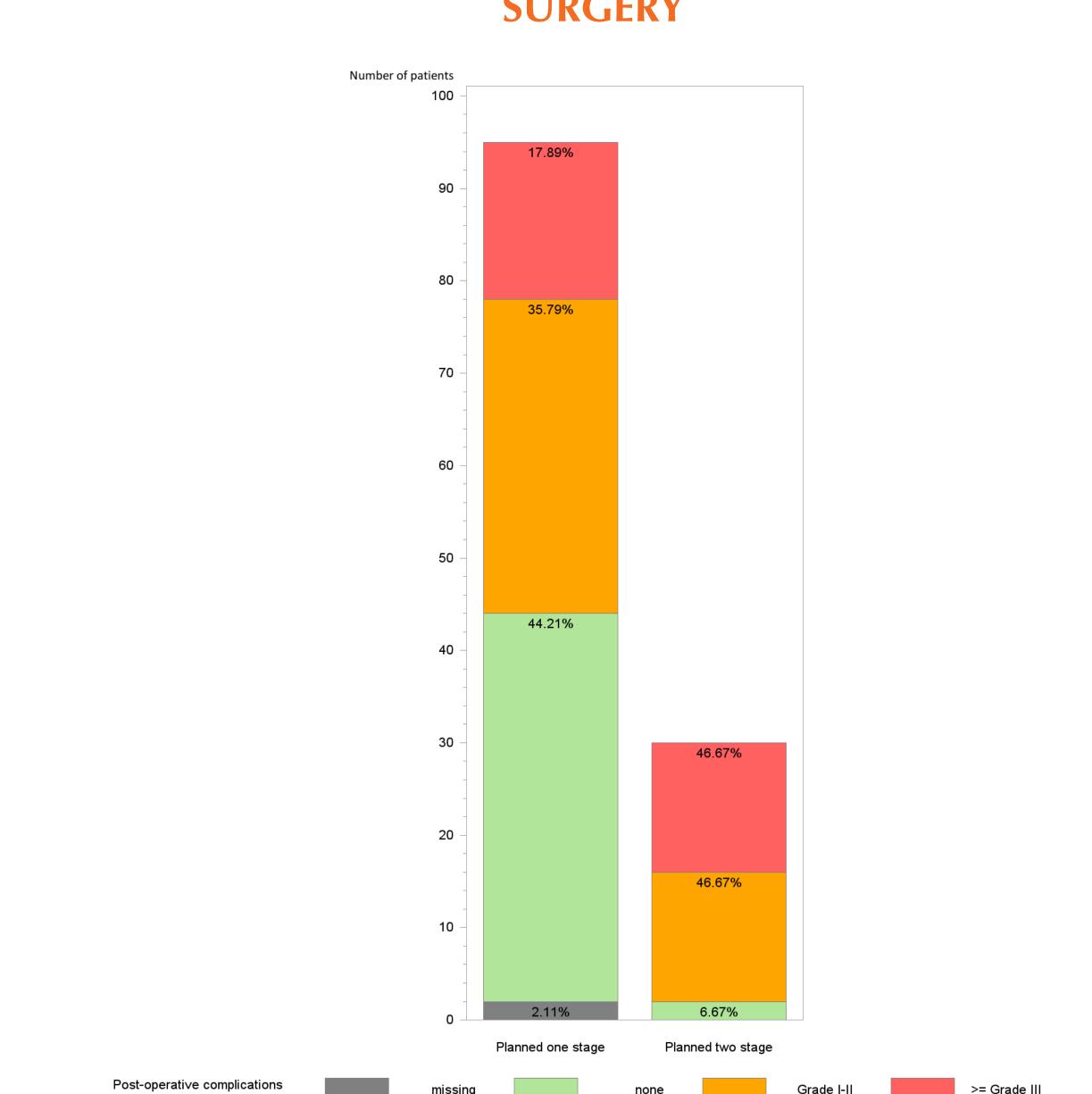
POSTOPERATIVE COMPLICATIONS PER TYPE OF LIVER SURGERY Over-all grading of complications by Clavien Dindo IVa patients with complications N (row %) Type of liver surgery 11 (11.6) 0 (0.0) 11 (11.6) 23 (24.2) 6 (6.3) One stage Planned two stage 28 (93.3) 14 (46.7) 8 (26.7) 3 (10.0) 1 (3.3) 2 (6.7)* 0 (0.0)0 (0.0)0 (0.0)1 (100.00) 0 (0.0) 1 (100.00) 0 (0.0)**Total number of patients** 11 (13.8%) 37 (46.3%) 14 (17.5%) 15 (18.8%) 1 (1.3%) 2 (2.5%)

*2 deaths occurred after associating liver partition and PV ligation (PVL) in staged hepatectomy (ALPPS) strategy





POSTOPERATIVE COMPLICATIONS BY TYPE OF LIVER SURGERY



	Type of liver surgery			
	Missing (N=1)	One stage (N=95)	Planned two stage (N=30)	Patients used in analysis (N=126)
	N (%)	N (%)	N (%)	N (%)
Post-hepatectomy liver failure				
Grade A	-	4 (4.2)	4 (13.3)	8 (6.3)
Grade B	-	_	2 (6.7)	2 (1.6)
Grade C	-	1 (1.1)	1 (3.3)	2 (1.6)
Biliary leakage				
Grade A	_	2 (2.1)	_	2 (1.6)
Grade B	-	7 (7.4)	5 (16.7)	12 (9.5)
Grade C	_	1 (1.1)	-	1 (0.8)
Abdominal infection/abscess	_	8 (8.4)	10 (33.3)	18 (14.3)
Biliary obstruction	_	_	1 (3.3)	1 (0.8)
Biloma	_	6 (6.3)	2 (6.7)	8 (6.3)
Gastrointestinal anastomotic leak	_	4 (4.2)	1 (3.3)	5 (4.0)
Hepatic infection/abscess	_	1 (1.1)	1 (3.3)	2 (1.6)
Intra-abdominal hemorrhage	-	2 (2.1)	1 (3.3)	3 (2.4)
Heart failure	_	_	_	_
Renal failure	_	_	2 (6.7)	2 (1.6)
Respiratory failure	_	_	2 (6.7)	2 (1.6)
Thromboembolic event	_	3 (3.2)	1 (3.3)	4 (3.2)
Urinary tract infection	_	7 (7.4)	6 (20.0)	13 (10.3)
Wound infection	1 (100.0)	4 (4.2)	7 (23.3)	12 (9.5)
Anemia	_	10 (10.5)	7 (23.3)	17 (13.5)
Infection	_	6 (6.3)	5 (16.7)	11 (8.7)
Fluid retention	_	6 (6.3)	3 (10.0)	9 (7.1)
lleus	_	2 (2.1)	3 (10.0)	5 (4.0)
Other post-operative complications	_	15 (15.8)	11 (36.7)	26 (20.6)

POSTOPERATIVE COMPLICATIONS -TYPE OF LIVER SURGERY

www.eortc.org
Trial number: NCT02218801

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