The Breast 23 (2014) 104-111

Contents lists available at ScienceDirect

The Breast

journal homepage: www.elsevier.com/brst

Quality of information reporting in studies of standard and oncoplastic breast-conserving surgery

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A R T I C L E I N F O

Article history: Received 18 August 2013 Received in revised form 30 November 2013 Accepted 7 December 2013

Keywords: Breast-conserving surgery Oncoplastic Outcomes Systematic review

ABSTRACT

The aim of this systematic review was to establish the completeness of reporting of key patient, tumour, treatment, and outcomes information in the randomized-controlled trials (RCTs) of standard breast-conserving surgery (sBCS) considered to be the 'gold-standard', and to compare this with the reporting of the same key criteria for all published studies of oncoplastic breast-conserving surgery (oBCS). Pubmed (1966 to 1st April 2013), Ovid MEDLINE (1966 to 1st April 2013), EMBASE (1980 to 1st April 2013), and the Cochrane Database of Systematic Reviews (Issue 4, 2013) were searched separately for the following terms: (i) 'oncoplastic AND breast AND surgery'; and (ii) 'therapeutic AND mammaplasty'. Only English language and full text articles were reviewed.

Following a pilot evaluation of all studies, key reporting criteria were identified. 16 RCTs of sBCS (n = 11,767 patients) were included, and 53 studies met the inclusion criteria for oncoplastic BCS (n = 3236 patients), none of which were RCTs. No study reported all of the criteria identified, with a mean of 64% of key criteria (range, 55–75%) reported in studies of sBCS, and 54% of criteria (range, 10–85%) reported in studies of oBCS. It is therefore evident that there is much room for improvement in the quality of reporting is BCS studies. Standards are proposed to give future studies of BCS a framework for reporting key information and outcomes.

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Introduction

The development of oncoplastic breast-conserving surgery (oBCS) has extended the role of standard breast-conserving surgery (sBCS) [1–4]. A plethora of oncoplastic techniques have been developed to allow parenchymal rearrangement or partial breast reconstruction in breasts with a high tumour-to-breast size ratio where mastectomy would traditionally be indicated. The oncological safety of oBCS, however, has yet to be fully established, with many studies limited by short-term follow-up [5]. In addition there has been concern that many published studies of oBCS are predominantly technique driven and do not fully report important oncological data, and without these it is difficult to appraise these studies individually or to perform pooled analysis of the results.

The information reported in RCTs of sBCS is regarded as the 'gold-standard'. The aim of this review was to establish the completeness of reporting of key patient, tumour, treatment, and outcomes data in the RCTs of sBCS and to compare this with the reporting of the same key criteria in all published articles of oBCS.

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Methods

Search methods for identification of studies

Pubmed (1966 to April 2013), Ovid MEDLINE (1966 to April 2013), EMBASE (1980 to April 2013), and the Cochrane Database of Systematic Reviews (Issue 4, 2013) were searched separately for the following terms: (i) 'oncoplastic AND breast AND surgery'; and (ii) 'therapeutic AND mammaplasty'. Only English language and full text articles were reviewed. Articles were then cross-referenced until the search strategy was exhausted. The latest search was performed on 1st April 2013.

Inclusion criteria

All of the published RCTs selected for the Early Breast Cancer Trialists' Collaborative Group (EBCTCG) meta-analysis of BCS were included as the best available evidence for sBCS [6]. oBCS studies that utilized volume displacement techniques, using parenchymal rearrangement either by standard reduction mammaplasty techniques or modifications using extended or secondary pedicles, or volume replacement techniques, by the use of local, regional, or free flaps, were included. No studies were excluded.



Review





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Table 2

Definition of key reporting and additional important criteria

After a pilot evaluation of the outcomes data reported in all studies of BCS, key reporting criteria were selected by the authors (Table 1). These key data were collected from all studies meeting the inclusion criteria, as well as additional surgical and follow-up data determined to be important by the authors, and an overall score was calculated based on reporting of these criteria and expressed as a percentage.

Levels of evidence

The studies included were classified into levels of evidence according to the Oxford Centre for Evidence-Based Medicine Levels of Evidence [7].

Results

More than 300 potentially relevant publications were identified using the search strategy and screened for retrieval by the first author.

Standard breast-conserving surgery studies

16 studies met the inclusion criteria for sBCS (n = 11,767 patients), all reporting level 1 evidence (Tables 2, 4 and 5) [8–23].

Oncoplastic breast-conserving surgery studies

53 studies met the inclusion criteria for oBCS (n = 3236 patients), none of which were RCTs, including 11 studies reporting level 2 evidence, 33 studies level 3, and 9 studies level 4 evidence (Tables 3–5) [24–76]. 41 studies reported volume displacement

Table 1

Key reporting and additional important criteria.

Key reporting criteria	
Demographic and tumour data	Number of patients included Patient age Tumour size Tumour type Oestrogen receptor status Tumour focality Tumour grade Nodal status
Surgical data	Minimum clear excision margin Number of incomplete excisions Study definition of a microscopic clear margin Number of procedures converted to mastectomy
Follow-up data	Mean follow-up Number of local and distant recurrences Mortality rate
Adjuvant therapy data	Whole breast radiotherapy delivery and dose Boost radiotherapy delivery and dose Marking of tumour bed and method used Other adjuvant treatments given
Additional important criteria	1
Surgical data	Breast size Resection weight Resultant breast size after radiotherapy
Follow-up data	Radiological follow-up Need for any procedure to exclude recurrence Cosmetic outcomes Secondary Revisions

	No. ⊿	Vge T si	ize T ty	rpe ER	Age T size T type ER Uni/multi- G Nodal	Nodal	Excision	Excision Incomplete	Clear	Conversion to Followup Recurrence	Followup	Recurrence		Mortality	DXT dose	Boost	Other	Tumour
	pts				Focal	status	margin	excision rate	margin mas definition rate	mastectomy rate		Local	Distant	1	and frcns	given and dose	adjuvant bed therapy maı	bed marking
blamey et al., 2013 [8] I	1135 Y	, ,	Y	z	۲ ۲	Y	z	z	۲	z	Y	Y	Y	Y	Y	Y (dose N)	Y	z
Spooner et al., 2012 [9]	707 Y	, Υ	Y	z	γ	Y	z	Z	z	Z	Y	Y	Y	Y	Y	Y	Υ	z
Winzer et al., 2010 [10]	347 Y	Y	Y	Y	γ	Y	z	Z	Y	Z	Y	Y	Y	Y	z	z	Υ	z
Holli et al., 2009 [11]	264 Y	Y	Υ	z	Y Y	Υ	Y	Z	Y	z	Y	Y	Y	Y	Y	z	Y	z
Potter et al., 2007 [12] 8	¥ 698	Y	z	Υ		Υ	z	Z	Y	z	Y	Y	Y	Y	Y	Y	Y	Υ
Prescott et al., 2007 [13]	255 Y		z	z	۸	Y	z	z	z	Z	Y	Y (15 mths	i) Y (15 mths)) Y (15 mths)) Y	Y	Y	z
Ford et al., 2006 [14]	400 Y		z	Υ	Z Z	۲	z	z	Y	Z	Y	Y	Y	Y	Y	Y	Y	z
Hughes et al., 2004 [15] (636 Y		z	Υ			z	z	z	Z	Y	Y	Y	Y	Y	Y	Y	z
	769 Y		z	Y	γ Υ	Y	z	Z	Y	Z	Y	Y	Y	Y	Y	Y	Υ	Υ
Malmstrom et al., 1	1187 Y	Y	z	Y		١Y	z	z	Z	z	Υ	Y	Y	Y	Y (frcns N)	Υ	Υ	Z
2003 [17]																		
Fisher et al., 2002 [18] 10	1009 Y	, Υ	z	Υ			z	z	Y	z	Y	Y	Y	Y	Y	Y	Y	z
Forrest et al., 1996 [19]	585 Y	Y	z	۲			z	z	z	Z	Y	Y	Y	Y	Y	Y	Y	z
Whelan et al., 1994 [20]	Υ 667		z	Υ	۸		z	z	z	Z	Y	Y	Y	Y	Y	Y	z	z
Liljegren et al., 1994 [21]	381 Y		z	z		١٢	z	Z	z	Z	Y	Y	Y	Y	Y	z	Υ	z
Veronesi et al., 1993 [22]	567 Y	Y	Y	z			z	Y	z	Z	Y	Y (39 mths)	s) Y (39 mths)) Y (39 mths)) Y	Y	Υ	z
Fisher et al., 1991 [23] 18	1857 Y		Y	Y	γ		z	Z	z	Z	Y	Y	Y	Y	Y	Y	Υ	z

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