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The Women's Recovery from Sternotomy (WREST) Study

A randomized trial of a novel undergarment for women's use following sternotomy

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Women's Recovery From Sternotomy Study

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Clinical trial registration number ISRCTN 47669580

King, K.M., et al. (2005). The women's recovery from sternotomy (WREST) study: The design of a randomized trial of a novel undergarment for early use following sternotomy. *Am Heart J*, 149(5), 761-7.
King, K.M., et al. (2006). Early use of a novel undergarment following sternotomy: The Women's Recovery from Sternotomy Trial (WREST). *Am Heart J*, 152, 1187-93.



Women's Recovery From Sternotomy Study

Background

- splinting is a common strategy used to assist post-op patients move
- clinicians often suggest that women use a supportive and comfortable brassiere post-operatively to reduce tension on incision—thereby reducing pain and discomfort
- recommendation is based largely on clinical experience
- empirical—clinical trial—evidence had not been offered as a foundation for this practice



Women's Recovery From Sternotomy Study

Primary Objective

To examine the effect of wearing a novel undergarment during the early post-sternotomy period on incision and breast pain and discomfort, as well as return to function

Secondary Objective

To monitor the safety of using the undergarment in the early post-sternotomy period.



Women's Recovery From Sternotomy Study

Intervention

- measured by site RAs pre-operatively for size
- donned as soon as clinically stable
- asked to wear undergarment as much as comfortable to do so

Usual Care

- no 'standard'
- women are often encouraged to bring own brassiere (donned approximately 2-3 days post-op; used as desired)
- no binding of breasts was permitted

WREST

Women's Recovery From Sternotomy Study



- made from nylon; has soft, absorbent flap behind zipper
- wide neckline, velcro straps at shoulders
- wide band at base does not roll--covers chest tubes comfortably
- wide back provides extra comfort



Women's Recovery From Sternotomy Study

Outcomes (over 12-weeks post-sternotomy)

- incision pain and discomfort* (numeric rating scales)
- breast pain and discomfort* (numeric rating scales)
- analgesic use
- functional status (Health Assessment Questionnaire)

- sternal wound healing
- antibiotic use

*(tingling, dull ache, numbness, itchiness, tenderness, other patient-identified factor)

WREST

Women's Recovery From Sternotomy Study

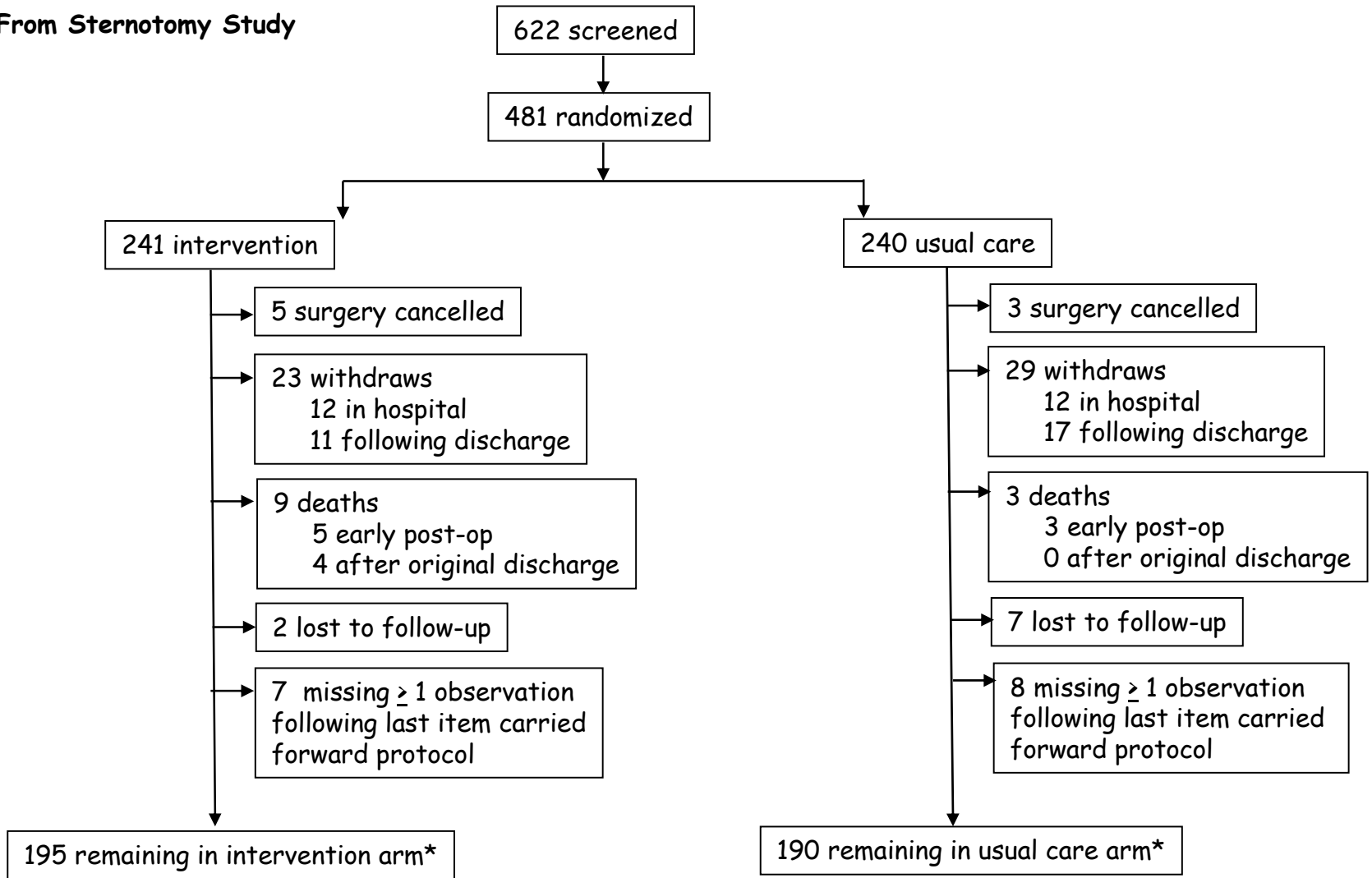


WREST STUDY SITES

481 participants from ten Canadian centres



Women's Recovery From Sternotomy Study



*original power analysis suggested 188 in each group to detect 20% difference in pain scores

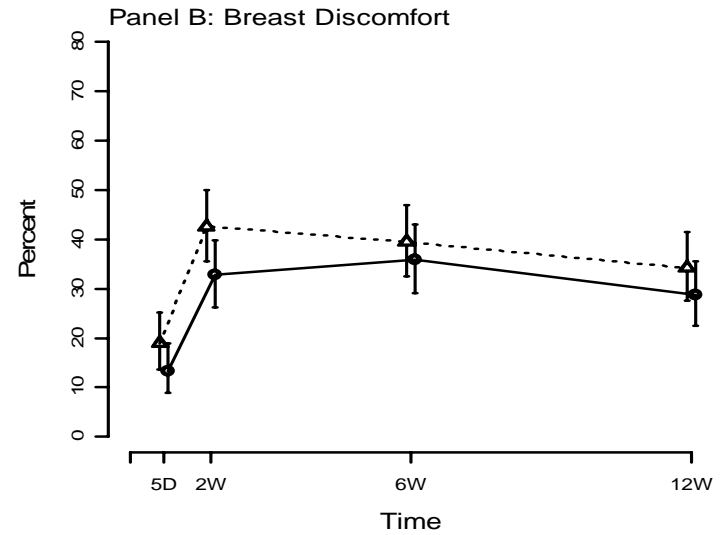
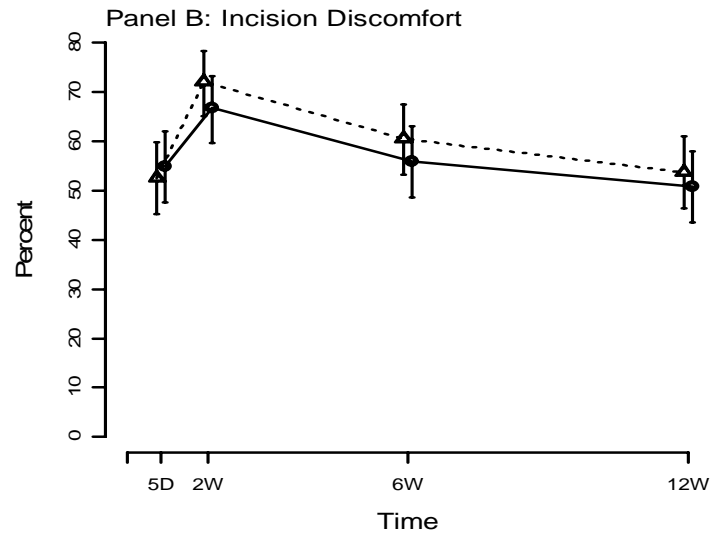
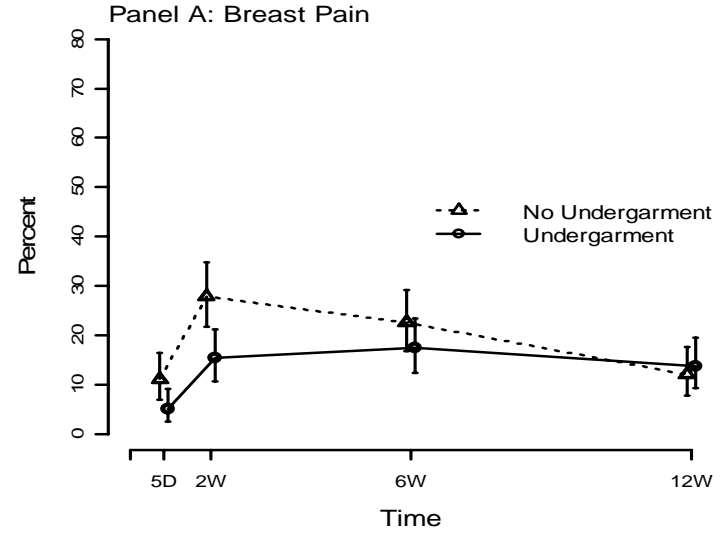
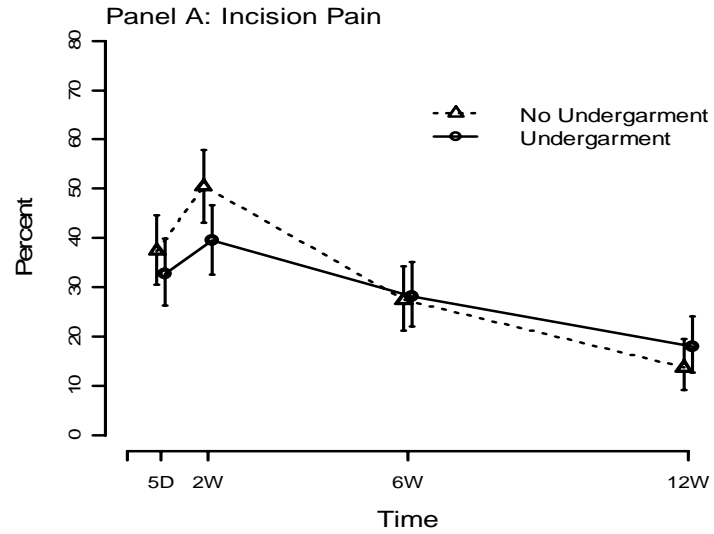


Women's Recovery From Sternotomy Study

Variable	Intervention	SD/%	Usual Care	SD/%
Age (Mean)	66.65	11.09	64.67	11.55
BMI (Mean)	29.09	6.60	28.82	5.14
Chest Circ (Mean)	39.15	3.96	38.87	4.24
Brassiere Cup Size				
A/B	79/195	40.5%	65/190	34.2%
C/D+	116/195	59.5%	125/190	65.8%
Study Brassiere Size				
XS -S (32-34")	9/195	4.6%	3/190	1.6%
M - L (36-38")	45/195	23.1%	52/190	27.4%
XL - 2XL (40-44")	95/195	48.7%	90/190	47.4%
3XL - 4XL (44-48"+)	46/195	23.6%	45/190	23.7%
Surgery Type				
CABG	112/195	57.4%	109/190	57.4%
CABG + Valve	13/195	6.7%	20/190	10.5%
Other	70/195	35.8%	60/190	32.1%
Donor Graft Site				
Right IMA	10/125	8.0%	15/129	11.6%
Left IMA	102/125	81.6%	109/129	84.5%
Wound Closure				
Staples	41/195	21.0%	37/190	19.5%
Sutures	137/195	70.3%	133/190	70.0%
Retention Sutures	4/195	2.1%	5/190	2.6%



Women's Recovery From Sternotomy Study





Women's Recovery From Sternotomy Study

Findings

- *post-hoc* analyses for day of discharge and over the three weeks following discharge revealed significantly reduced likelihood of breast pain (OR 0.46 [0.32-0.66]; $p < 0.001$), and breast discomfort (OR 0.62 [0.44-0.86]; $p = 0.0045$)
- no differences in functional status, analgesic use, antibiotic use, wound healing
- findings not influenced by age or brassiere cup size



Women's Recovery From Sternotomy Study

Conclusions

- using a supportive undergarment during the early post-operative period reduces breast, but not incision pain
- this finding is amplified and extends to include a reduction in breast discomfort, when women are discharged within 14 post-operative days



Women's Recovery From Sternotomy Study

Sub-studies...

WREST-Econ—An economic analysis of the undergarment's use

WREST-E—An extension study to examine outcomes at 12-months post-operatively

WREST-Scar—A photographic analysis of the impact of the undergarment on sternal scar formation

WREST-Scar-Qual—A qualitative investigation of the impact of sternal scarring



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Women's Recovery From Sternotomy Study



Women's Recovery From Sternotomy Extension Sub-Study

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King, K.M., et al. (in review). Women's Recovery from Sternotomy-Extension (WREST-E) Study: Examining long-term pain and discomfort following sternotomy and their predictors. Heart.



Women's Recovery From Sternotomy Extension Sub-Study

Purposes

- describe the longer term outcomes of WREST women
- examine the extent to which pain and discomfort in the early recovery period (5 days and 12-weeks) and clinical variables predict outcomes at the 12th post-operative month

Outcomes

- incision and breast pain and discomfort



WREST-E

Women's Recovery From Sternotomy Extension Sub-Study

Variable	Mean/N	SD/%
Age (Mean)	66.35	11.17
BMI (Mean)	29.24	6.33
Chest Circ. (Mean)	39.11	4.21
Brassiere Cup Size		
A/B	110/326	33.7%
C/D+	216/326	66.3%
Study Brassiere Size		
XS - S (32-34")	12/326	3.7%
M - L (36-38")	82/326	25.1%
XL - 2XL (40-44")	154/326	47.3%
3XL - 4XL (44-48+")	78/326	23.9%
Surgery Type		
CABG	192/326	58.9%
CABG + Valve	29/326	8.9%
Other	105/326	32.2%
Donor Graft Site		
Left only IMA	185/221	83.7%
Bilateral IMA	19/221	8.6%
Wound Closure		
Staples	70/326	21.5%
Sutures	230/326	70.6%
Retention Sutures	9/326	2.8%

WREST-E

Women's Recovery From Sternotomy Extension Sub-Study

OUTCOMES at 12-months	N=326	%
Pain		
Incision	40	12.3%
Breast	28	8.6%
Discomfort		
Incision	133	40.8%
Breast	73	22.4%

Crude and adjusted logistic regression models for outcomes at 12-post-operative months

Outcome	Independent Predictor	Crude Model OR (95% CI)	Adjusted Model OR (95% CI)
incision pain			
	incision discomfort at 12-wks	3.21 (1.54-6.67)	3.10 (1.47-6.55)
breast pain			
	breast discomfort at 5-days	4.63 (1.77-12.11)	4.21 (1.61-11.04)
	breast discomfort at 12-wks	10.21 (4.12-25.28)	10.19 (4.07-25.53)
incision discomfort			
	incision pain at 5-days	1.78 (1.07-2.97)	1.83 (1.08-3.10)
	breast pain at 12-wks	3.10 (1.32-7.25)	3.33 (1.40-7.93)
	incision discomfort at 12-wks	4.24 (2.59-6.93)	4.77 (2.86-7.98)
breast discomfort			
	incision discomfort at 12-wks	2.94 (1.54-5.61)	2.94 (1.54-5.61)
	breast discomfort at 12-wks	4.79 (2.63-8.73)	4.79 (2.63-8.73)
any pain or discomfort			
	any pain or discomfort at 12-wks	4.62 (2.88-7.41)	4.59 (2.86-7.38)

Adjusted step-wise logistic regression models for outcomes at 12-post-operative months

Outcome	Clinical Predictor	Adjusted Model OR (95% CI)
incision pain		
	chest circumference	1.12 (1.03-1.21)
breast pain	bilateral IMA donor grafts	4.32 (1.47-12.70)
	left only IMA donor graft	2.75 (1.01-7.44)
incision discomfort		
	surgery other than CABG and/or valve	5.82 (1.75-19.33)
breast discomfort	bilateral IMA donor grafts	3.19 (1.08-9.39)
	none	
any pain or discomfort		
	chest circumference	1.11 (1.03-1.20)
	bilateral IMA donor grafts	4.77 (1.61-14.15)



Women's Recovery From Sternotomy Extension Sub-Study

Conclusions

- incision and breast pain and discomfort as long as 12-months post-sternotomy is a significant problem
- pain and discomfort at 12-weeks post-sternotomy and not necessarily in the early post-operative course (i.e., 5-days as previously thought), may be predictive of longer-term symptoms
- bilateral IMA graft use may be predictive of longer-term symptoms



Women's Recovery From Sternotomy Study

Not without methodologic challenges!



To provide best evidence for patient care...