

Evidence Profile Q3: *Supporting adults who anticipate or live with an ostomy, Second edition*

Research Q3 Evidence Profile (Quantitative)

Question 3: Should prevention strategies for parastomal hernia development or no prevention strategies for parastomal hernia development be recommended?

Population: All adults (18 & over) living with or anticipating an ostomy.

Intervention: Prevention strategies for parastomal hernia development.

Comparison: No prevention strategies for parastomal hernia development.

Outcomes: Rates of parastomal hernia.

Setting: All healthcare settings

Bibliography: 1489, 2991

Quality assessment							Study details		No. of participants		Reported effects/outcomes	Certainty	Reference
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Country	Parastomal hernia prevention intervention	Hernia prevention intervention	No hernia prevention intervention			
Rates of parastomal hernia (measured objectively)													
1	Quasi-experimental (prospective study with retrospective comparison)	very serious ^a	not serious	serious ^b	serious ^c	none	1489: UK	Intervention programme included advice on wearing lightweight support garments as well as an abdominal exercise programme to start immediately.	15/100 (0.15%)	No true comparison group. Rates of hernia in study participants were compared to 23 per cent local incidence and 44 per cent overall incidence reported in existing studies.	Overall, the study reported that the incidence of parastomal hernia was 15 per cent in all study participants and 1 per cent among those who were fully compliant to the program. However, the study did not provide details regarding measures taken to ensure compliance. Details of comparison groups to which the incidence of hernia were compared to were also lacking. It is unclear if the comparison group participants only received usual care.	⊕○○○ VERY LOW	1489:North (2014)
4	Systematic	serious ^d	not serious	serious ^e	serious ^f	none	2991: UK, Israel &	Two out of five individual studies	Thompson &	Thompson &	Thompson & Trainor (2005): For every 1000	⊕○○○	(De Raet et al., 2008;

Quality assessment							Study details		No. of participants		Reported effects/outcomes	Certainty	Reference
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Country	Parastomal hernia prevention intervention	Hernia prevention intervention	No hernia prevention intervention			
	Review						Belgium	<p>within the systematic review examined a parastomal hernia prevention programme for patients after stoma surgery (Thompson and Trainor, 2005; 2007).</p> <p>One individual study evaluated preoperative stoma site marking on the incidence of hernia (Person et al., 2012)</p> <p>One individual study assessed the correlation between optimal body mass index (BMI), waist circumference and parastomal herniation (De Raet et al., 2008).</p>	<p>Trainor (2005) 16/114 (14%)</p> <p>Thompson & Trainor (2007) 17/99 (17%)</p> <p>(Person et al., 2012) 3.8 / 52 (7%)</p> <p>(De Raet et al., 2008) 22/41 (reported no hernia when mean BMI was 24.5) 22/41 (reported no hernia when mean waist</p>	<p>Trainor (2005) 24/87 (28%)</p> <p>Thompson & Trainor (2007) 24/87 (28%)</p> <p>(Person et al., 2012) 24.5 / 53 (46%)</p> <p>(De Raet et al., 2008) 19/41 (reported hernia when mean BMI was 28.2) 19/41 (reported hernia when mean</p>	<p>people who receive parastomal hernia prevention programme, 13 fewer will develop parastomal hernia (ranges from 30 fewer to 3 more based on confidence intervals).</p> <p>Thompson & Trainor (2007): For every 1000 people who receive parastomal hernia prevention programme, 10 fewer will develop parastomal hernia (ranges from 25 fewer to 6 more based on confidence intervals).</p> <p>(Person et al., 2012): For every 1000 people who receive pre-operative stoma site marking, 40 fewer will develop parastomal hernia (ranges from 88 fewer to 8 more based on confidence intervals).</p> <p>(De Raet et al., 2008): When BMI is less than 24.5 and waist circumference less than 100, there is a less chance of developing parastomal hernia.</p>	VERY LOW	Person et al., 2012; Thompson & Trainor, 2005, 2007) as cited in [Bland & Young, 2015]).

Quality assessment							Study details		No. of participants		Reported effects/outcomes	Certainty	Reference
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Country	Parastomal hernia prevention intervention	Hernia prevention intervention	No hernia prevention intervention			
									circumference was 94)	waist circumference was 105).			

Explanations

- a. Based on the ROBINS-I tool for quasi-experimental studies, this study had very serious concerns related to risk of bias due to limitations in how the study was conducted. We downgraded by 1.5.
- b. No details about control group provided; unable to assess if control group received only usual care. Therefore, study was downgraded 0.5 points for indirectness.
- c. The total number of events (persons who developed hernia) for the study was less than 300 (optimal number of events). Therefore, the study was downgraded by 0.5 points.
- d. Based on the ROBINS-I tool for quasi-experimental studies, the individual studies (within the systematic review) had serious concerns related to risk of bias due to limitations in how the studies were conducted. We downgraded by 1.
- e. It is unclear if the comparison group received only usual care in the included studies. So downgraded by 0.5.
- f. The total number of events (persons who developed hernia) for the study was less than 300 (optimal number of events). Therefore, the study was downgraded by 0.5 points.