## Parastomal Hernia: the ultimate challenge to quality of life

Prof Neil Smart MBBS (Hons) PhD FRCSEd FEBS-AWS

Consultant Colorectal Surgeon, Royal Devon & Exeter Hospital Associate Professor, University of Exeter Medical School



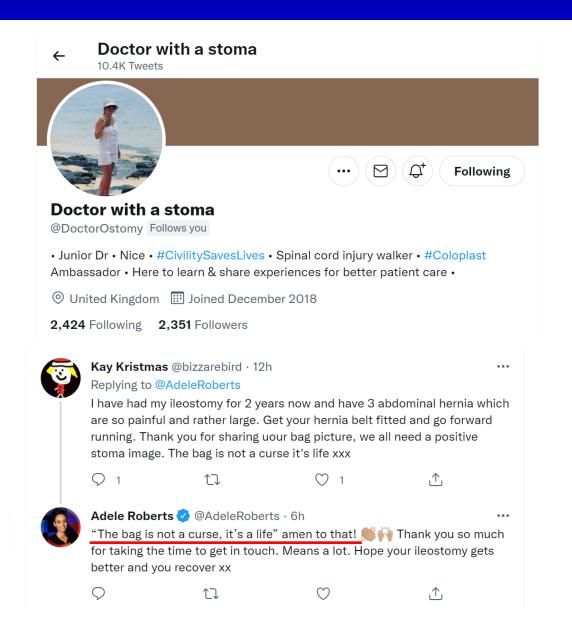
drneilsmart@hotmail.com

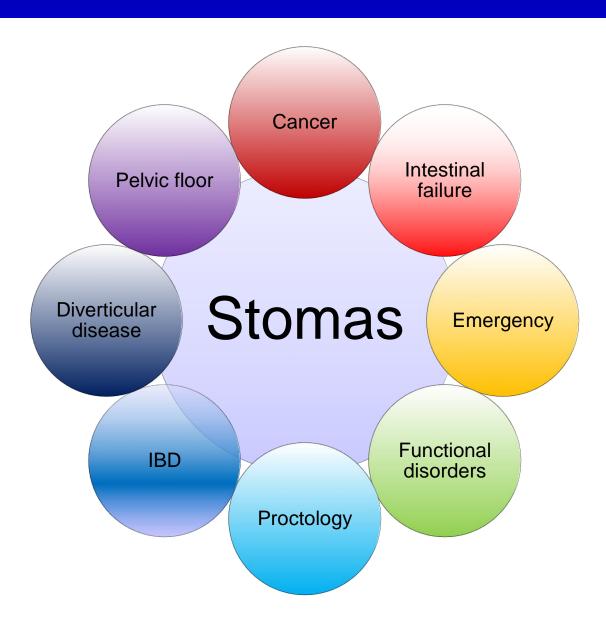




# Why are parastomal hernias important?

## STOMAS ARE THE COMMON GROUND





## PARASTOMAL HERNIA

Hernia DOI 10.1007/s10029-013-1162-z

ORIGINAL ARTICLE

#### European Hernia Society classification of parastomal hernias

M. Śmietański · M. Szczepkowski · J. A. Alexandre · D. Berger · K. Bury · J. Conze · B. Hansson · A. Janes · M. Miserez · V. Mandala · A. Montgomery · S. Morales Conde · F. Muysoms

#### Definition of a parastomal hernia

Following the EHS definition of ventral hernia (Any abdominal wall gap with or without a bulge in the area of a postoperative scar perceptible or palpable by clinical examination or imaging [1]), PH is an abnormal protrusion of the contents of the abdominal cavity through the abdominal wall defect created during placement of a colostomy, ileostomy or ileal conduit stoma [3]. It should be distinguished from local stoma problems without a hernia sac, such as a mucosal prolapse or a Siphon loop, which is a subcutaneous folding of the excess bowel length at the stoma.



## PARASTOMAL HERNIA

Hernia DOI 10.1007/s10029-013-1162-z

ORIGINAL ARTICLE

#### European Hernia Society classification of parastomal hernias

M. Śmietański · M. Szczepkowski · J. A. Alexandre · D. Berger · K. Bury · J. Conze · B. Hansson · A. Janes · M. Miserez · V. Mandala · A. Montgomery · S. Morales Conde · F. Muysoms

#### Definition of a parastomal hernia

Following the EHS definition of ventral hernia (Any abdominal wall gap with or without a bulge in the area of a postoperative scar perceptible or palpable by clinical examination or imaging [1]), PH is an abnormal protrusion of the contents of the abdominal cavity through the abdominal wall defect created during placement of a colostomy, ileostomy or ileal conduit stoma [3]. It should be distinguished from local stoma problems without a hernia sac, such as a mucosal prolapse or a Siphon loop, which is a subcutaneous folding of the excess bowel length at the stoma.



## PARASTOMAL HERNIA

Surgical repair of parastomal bulging: a retrospective register-based study on prospectively collected data doi:10.1111/codi.15197

M. Krogsgaard\*'† D, I. Gögenur‡, F. Helgstrand‡, R. M. Andersen\*'†, A. K. Danielsen†'§ D, A. Vinther¶\*\*, T. W. Klausen††, J. Hillingsø\*, B. M. Christensen\* and T. Thomsen§'‡‡

The classification of parastomal bulging comprises patients with a 'true' parastomal hernia and/or subcutaneous prolapse; it is, however, difficult to differentiate the two clinically [1,2,4,5]. Patients' symptoms are likely to be overlapping [1,5] and affect their everyday lives [6] and health-related quality of life [7].

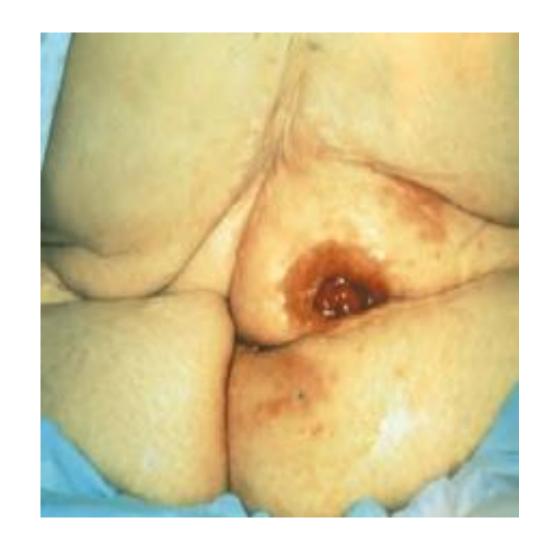


## **HOW COMMON IS IT?**

- ~1200000 ostomates
- 20000 new stomas per year
- 50% will be permanent (Black P, Br J Nurs 2009)



- 25% prevalence of clinical PSH
- Mean time to onset 18/12 (Ripoche J Visc Surg 2011)



## **HOW COMMON IS IT?**

- An inevitability?
- Depends upon follow up:

Duration (most within 2yr)
Risk life long
Type – clinical v radiological

Depends upon stoma type

colostomy > ileostomy end > loop



## **CLASSIFICATION OF PSH**

- Allows common language
- Facilitates comparisons
- Classifications:

Clinical

**Imaging** 

Intra-operative



Table 1 Description of previous parastomal hernia classification proposals

| Author (year)                              | Classification type | Classification based on | Number of subclasses | Clinical validation |
|--|---------------------|-------------------------|----------------------|---------------------|
| Devlin [5]                                 | Intraoperative      | Intraoperative findings | 4                    | Yes                 |
| Rubin [4]                                  | Intraoperative      | Intraoperative findings | 4                    | No                  |
| Moreno-Matias [6]                          | Radiological        | CT                      | 5                    | Yes                 |
| Gil, Szczepkowski [Bielanski Hospital] [8] | Clinical            | Physical examination    | 4                    | Yes                 |

## EHS CONSENSUS 2013

| Parastom              | HS<br>nal Hernia<br>fication | Small<br>≤ 5 cm | <b>Large</b> > 5 cm |   |
|-----------------------|------------------------------|-----------------|---------------------|---|
| Concomitant           | No                           | I               | III                 | A |
| incisional<br>hernia? | Yes                          | II              | IV                  |   |
|                       |                              | P               | R                   |   |

## **COMPLEX SITUATION?**

"Complex abdominal wall hernia"

Multiple abdominal wall herniae incisional & parastomal

Concurrent intestinal disease (e.g. Crohn's / cancer)

Fistula

Infection

Co-morbidity / obesity

**Domain loss** 



## PROBLEM? TRADITIONAL SURGICAL DOGMA

- "Most parastomal hernias are minimally symptomatic..." RK Pearl, WJS 1989
- Cook County experience 1976 1995: Park et al DCR 1999

**Table 2.**Overall Incidence of the Different Types of Complications

| Early Complications          | No. of Complications | Incidence<br>(%) | Late Complications           | No. of<br>Complications | Incidence<br>(%) |  |
|------------------------------|----------------------|------------------|------------------------------|-------------------------|------------------|--|
| Skin irritation              | 199                  | 12.31            | Skin irritation              | 92                      | 5.69             |  |
| Poor location                | 111                  | 6.87             | Prolapse                     | 28                      | 1.73             |  |
| Parital necrosis             | 83                   | 5.14             | Stenosis                     | 27                      | 1.67             |  |
| Retraction                   | 73                   | 4.52             | Parastomal hernia            | 19                      | 1.18             |  |
| Parastomal separation        | 64                   | 3.96             | Pseudoepithelial hyperplasia | 18                      | 1.11             |  |
| Parastomal abcess            | 35                   | 2.17             | Retraction                   | 17                      | 1.05             |  |
| Bleeding                     | 12                   | 0.74             | Allergy                      | 5                       | 0.31             |  |
| Complete necrosis            | 6                    | 0.37             | Perforation                  | 1                       | 0.06             |  |
| Evisceration                 | 6                    | 0.37             |                              |                         |                  |  |
| Stenosis                     | 4                    | 0.25             |                              |                         |                  |  |
| Pseudoepithelial hyperplasia | 4                    | 0.25             |                              |                         |                  |  |
| Protruding sigmoid           | 2                    | 0.12             |                              |                         |                  |  |
| Allergy                      | 1                    | 0.06             |                              |                         |                  |  |
| Total                        | 600                  |                  |                              | 207                     |                  |  |

## PROBLEM? ASK THE PATIENT!

France Rig

Ripoche et al J Visc Surg 2011

- Only 24% are asymptomatic
- Up to 30% require surgery

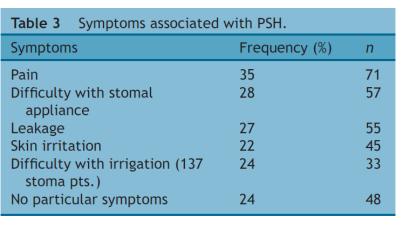
Denmark

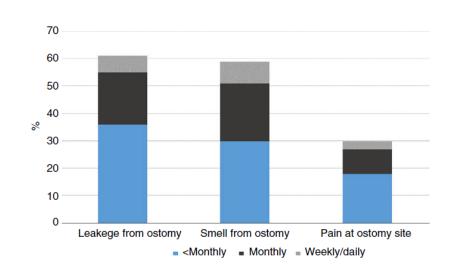
Feddern et al CODI 2015

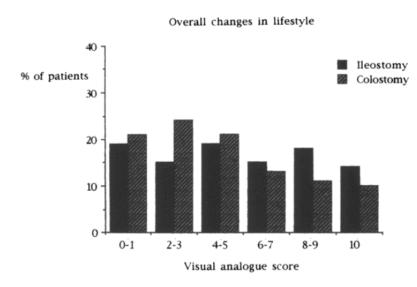
PSH 57% of 644 ostomates

UK Nugent et al DCR 1999

> 40% incidence - impact ++







## NEGATIVE IMPACT ON QOL

## Parastomal Hernia: Impact on Quality of Life?

Sven M. van Dijk<sup>1</sup> · Lucas Timmermans<sup>1</sup> · Eva B. Deerenberg<sup>1</sup> · Bas Lamme<sup>2</sup> · Gert-Jan Kleinrensink<sup>3</sup> · Johannes Jeekel<sup>3</sup> · Johan F. Lange<sup>1</sup>

Table 5 Multivariate analysis

| Effect of parastomal hernia on SF-36, EQ-5D and BIQ components (scale) | Mean difference (95 % confidence interval) | p value |
|--|--|---------|
| Equation 5D pain (0–1)   | 0.25 (0.072 to 0.425)                      | 0.006   |
| SF36 physical functioning (0–100)                                      | -10.2 (-19.5 to -0.858)                    | 0.033   |
| SF35 Role physical (0–100)   | -13.4 (-30.1 to 3.2)                       | 0.113   |
| SF36 Bodily pain (0-100)   | -11.3 (-19.8  to  -2.8)                    | 0.009   |
| SF36 General health (0-100)  | -9.0 (-16.6  to  -1.4)                     | 0.021   |
| SF36 physical component score (0-100)                                  | -4.8 (-8.8  to  -0.8)                      | 0.020   |
| BIQ Shame of scar (1-4)  | -0.4 (-0.6  to  -0.1)                      | 0.010   |
| BIQ Describe the scar (1-10)   | -0.4 (-0.8  to  0.1)                       | 0.101   |
|  |  |         |

Data shown are differences between PH and no-PH group, adjusted for age, BMI, length of incision, and surgical complications p values < 0.05 are shown in italics

## PSH IMPACT ON QOL

## Impact of a Parastomal Bulge on Quality of Life – A Cross-sectional Study of Patients From the Danish Stoma Database

Marianne Krogsgaard, MHS,\*†⊠ Torquil Watt, DMSc,‡ Anne K. Danielsen, PhD,†
Tobias Wirenfeldt Klausen, MSc,§ Anders Vinther, PhD,¶ Ismail Gögenur, DMSc,||
and Thordis Thomsen, PhD\*\*

TABLE 2. Mean and Adjusted Mean Differences in Health-related Quality of Life (HRQoL) Scores Between Patients With and Without a Self-reported Parastomal Bulge

| Scale/Subscale             | Bulge $(n = 693)$ | No Bulge $(n = 565)$ | Linear Regression <sup>†</sup> Ref. No Bulge | Effect Size           |  |
|----------------------------|-------------------|----------------------|--|-----------------------|--|
| SF-36                      | Mean (SD)         | Mean (SD)            | Adjusted Mean Difference (95% CI)            | Cohens d <sup>‡</sup> |  |
| Physical Functioning       | 65 (28)           | 72 (30)              | -5 (-8; -2)**                                | 0.17                  |  |
| Role-Physical              | 57 (34)           | 67 (38)              | $-8 (-12; -4)^{***}$                         | 0.25                  |  |
| Bodily Pain                | 72 (29)           | 75 (29)              | $-7(-10; -3)^{***}$                          | 0.23                  |  |
| General Health             | 56 (24)           | 60 (26)              | $-6(-9; -3)^{***}$                           | 0.23                  |  |
| Vitality                   | 54 (25)           | 59 (25)              | $-7(-10; -4)^{***}$                          | 0.28                  |  |
| Social Functioning         | 78 (28)           | 82 (26)              | $-7(-10; -4)^{***}$                          | 0.26                  |  |
| Role-Emotional             | 66 (33)           | 74 (32)              | $-5(-9;-1)^{**}$                             | 0.16                  |  |
| Mental Health              | 72 (22)           | 75 (20)              | $-4(-7; -2)^{***}$                           | 0.21                  |  |
| SF-36 summary scores       |                   |                      |  |                       |  |
| Physical Component summary | 46 (10)           | 48 (11)              | $-3(-4;-1)^{***}$                            | 0.26                  |  |
| Mental Component summary   | 48 (12)           | 50 (11)              | $-2(-4;-1)^{***}$                            | 0.21                  |  |
| Stoma-QOL summary score    | 62 (23)           | 70 (20)              | -9 (-12; -7)***                              | 0.44                  |  |

**TABLE 3.** Mean and Adjusted Mean Differences in Health-related Quality of Life (HRQoL) Among Patients With and Without a Parastomal Bulge, Presented Separately for Patients With an Underlying Malignant or Benign Diagnosis

|                            | Malignant Diagnosis  |                               |   |  | Benign o                         |   |  |
|----------------------------|--|-------------------------------|---|--|----------------------------------|---|--|
| Scale/Subscale             | $\begin{array}{c} Bulge \\ n = 417^{\ddagger} \end{array}$ | No Bulge $n = 300^{\ddagger}$ | Linear Regression <sup>¶</sup><br>Ref. No Bulge | $\begin{array}{c} \textbf{Bulge} \\ \mathbf{n} = 276^{\S} \end{array}$ | No Bulge<br>n = 265 <sup>§</sup> | Linear Regression <sup>¶</sup><br>Ref. No Bulge | Interaction, Bulging<br>Status and Diagnosis |
| SF-36                      | Mean<br>(SD)   | Mean<br>(SD)                  | Adjusted Mean<br>Difference (95 % CI)           | Mean<br>(SD)   | Mean<br>(SD)                     | Adjusted Mean<br>Difference (95% CI)            | P-value                                      |
| Physical Functioning       | 69 (26)  | 74 (28)                       | -4 (-8; 0)                                      | 59 (30)  | 71 (30)                          | -7 (-12; -2)**                                  | 0.407  |
| Role-Physical              | 61 (32)  | 70 (34)                       | $-7 (-12; -2)^{**}$                             | 51 (35)  | 64 (34)                          | $-11 (-17; -4)^{**}$                            | 0.600  |
| Bodily Pain                | 77 (26)  | 80 (28)                       | -3(-8;1)  | 64 (31)  | 70 (29)                          | $-10 (-15; -5)^{***}$                           | 0.087  |
| General Health             | 61 (24)  | 65 (24)                       | $-5(-9;-1)^{**}$                                | 49 (24)  | 54 (27)                          | $-7 (-12; -2)^{**}$                             | 0.715  |
| Vitality                   | 59 (23)  | 63 (24)                       | $-4 (-8; -1)^*$                                 | 47 (25)  | 55 (25)                          | $-11 (-15; -6)^{***}$                           | 0.081  |
| Social Functioning         | 82 (26)  | 85 (25)                       | -3(-7;1)  | 71 (30)  | 79 (27)                          | $-12 (-18; -7)^{***}$                           | 0.019*                                       |
| Role-Emotional             | 69 (31)  | 75 (32)                       | -4(-9;1)  | 62 (35)  | 72 (32)                          | $-7(-13; -1)^*$                                 | 0.582  |
| Mental Health              | 76 (20)  | 77 (20)                       | -2(-5; 2)                                       | 66 (23)  | 73 (20)                          | $-8 (-12; -4)^{***}$                            | $0.011^*$                                    |
| SF-36 summary scores       |  |                               |   |  |                                  |   |  |
| Physical Component summary | 47 (9)   | 50 (10)                       | $-2(-4;-1)^{**}$                                | 43 (10)  | 46 (11)                          | $-3 (-5; -1)^{**}$                              | 0.581  |
| Mental Component summary   | 50 (11)  | 51 (11)                       | -1(-3;1)  | 45 (13)  | 48 (11)                          | $-4 (-7; -2)^{***}$                             | $0.038^*$                                    |
| Stoma-QOL summary score    | 64 (23)  | 73 (20)                       | $-9 (-12; -5)^{***}$                            | 58 (23)  | 66 (21)                          | $-10 (-13; -6)^{***}$                           | 0.529  |

**TABLE 4.** Mean and Adjusted Mean Differences in Health-related Quality of Life (HRQoL) Among Patients With and Without a Parastomal Bulge, Presented Separately for Patients With a Colostomy or an Ileostomy

|                            | Colostomy  |  |                                      | Heostomy   |                       |                                      |   |  |
|----------------------------|--|--|--------------------------------------|--|-----------------------|--------------------------------------|---|--|
| Scale/Subscale             | $\begin{array}{c} Bulge \\ n = 533^{\ddagger} \end{array}$ | $\begin{array}{c} No~Bulge\\ n=315^{\ddagger} \end{array}$ | Linear Regression¶<br>Ref No Bulge   | $\begin{array}{c} Bulge \\ n=160^{\S} \end{array}$ | No Bulge $n=250^{\$}$ | Linear Regression¶<br>Ref. No Bulge  | Interaction, Bulging Status<br>and Type of Stoma <sup>†</sup> |  |
| SF-36                      | Mean<br>(SD)   | Mean<br>(SD)   | Adjusted Mean<br>Difference (95% CI) | Mean<br>(SD)                                       | Mean<br>(SD)          | Adjusted Mean<br>Difference (95% CI) | P-value   |  |
| Physical Functioning       | 65 (28)  | 70 (32)  | -3 (-7; 1)                           | 64 (28)  | 75 (26)               | -9 (-14; -4)***                      | 0.110   |  |
| Role-Physical              | 59 (33)  | 67 (35)  | $-6 (-10; -1)^*$                     | 51 (35)  | 67 (32)               | $-13(-20; -6)^{***}$                 | 0.214   |  |
| Bodily Pain                | 74 (28)  | 77 (29)  | $-5 (-9; -1)^*$                      | 63 (31)  | 73 (28)               | $-10 (-16; -5)^{***}$                | 0.063   |  |
| General Health             | 58 (23)  | 63 (26)  | $-4 (-8; -1)^*$                      | 49 (26)  | 56 (26)               | $-9 (-15; -3)^{**}$                  | 0.248   |  |
| Vitality                   | 57 (24)  | 61 (25)  | $-5 (-8; -1)^{**}$                   | 48 (26)  | 57 (24)               | $-12(-17; -7)^{***}$                 | 0.095   |  |
| Social Functioning         | 80 (27)  | 83 (27)  | -3(-7;1)                             | 69 (31)  | 81 (26)               | $-14(-20; -8)^{***}$                 | 0.005**   |  |
| Role-Emotional             | 68 (33)  | 73 (34)  | -3 (-8; 2)                           | 63 (35)  | 74 (30)               | $-10 (-16, -3)^{**}$                 | 0.219   |  |
| Mental Health              | 73 (21)  | 75 (20)  | -2(-5;1)                             | 67 (24)  | 74 (20)               | $-9 (-14; -5)^{***}$                 | 0.017*  |  |
| SF-36 summary scores       |  |  |                                      |  |                       |                                      |   |  |
| Physical Component summary | 46 (9)   | 48 (11)  | $-2 (-3; -0.3)^*$                    | 43 (10)  | 48 (10)               | $-4 (-6; -2)^{***}$                  | 0.141   |  |
| Mental Component summary   | 48 (11)  | 50 (11)  | -1 (-3; 1)                           | 45 (13)  | 49 (11)               | $-5(-7; -3)^{***}$                   | 0.034*  |  |
| Stoma-QOL summary score    | 64 (22)  | 71 (21)  | $-7 (-11; -4)^{***}$                 | 55 (23)  | 68 (20)               | $-13 (-17; -9)^{***}$                | 0.095   |  |

**TABLE 5.** Mean and Adjusted Mean Differences in Health-related Quality of Life (HRQoL) Scores Between Patients With a Large (>10 cm) and a Small (< 10 cm) Self-reported Parastomal Bulge

| Scale/Subscale             | Large Bulge (n = 296) | Small Bulge $(n = 397)$ | Linear Regression† Ref. Small Bulge | Effect Size |
|----------------------------|-----------------------|-------------------------|-------------------------------------|-------------|
| SF-36                      | Mean (SD)             | Mean (SD)               | Adjusted Mean Difference (95% CI)   | Cohens d‡   |
| Physical Functioning       | 60 (28)               | 69 (27)                 | -7 (-11; -3)**                      | 0.24        |
| Role-Physical              | 51 (34)               | 61 (33)                 | $-9(-14; -4)^{***}$                 | 0.27        |
| Bodily Pain                | 69 (29)               | 74 (28)                 | $-8(-12; -3)^{***}$                 | 0.26        |
| General Health             | 52 (24)               | 60 (24)                 | $-7(-11; -4)^{***}$                 | 0.31        |
| Vitality                   | 51 (25)               | 57 (24)                 | $-7(-11; -4)^{***}$                 | 0.30        |
| Social Functioning         | 75 (29)               | 80 (27)                 | $-6(-10;-1)^{**}$                   | 0.21        |
| Role-Emotional             | 60 (35)               | 71 (31)                 | $-8(-14; -3)^{**}$                  | 0.26        |
| Mental Health              | 68 (24)               | 75 (20)                 | $-7(-10; -4)^{***}$                 | 0.33        |
| SF-36 summary scores       |                       |                         |                                     |             |
| Physical Component summary | 44 (10)               | 47 (9)                  | $-3(-4;-1)^{***}$                   | 0.30        |
| Mental Component summary   | 46 (12)               | 49 (11)                 | $-4 (-5; -2)^{***}$                 | 0.31        |
| Stoma-QOL summary score    | 58 (23)               | 64 (22)                 | $-8(-11; -4)^{***}$                 | 0.34        |

## PSH IMPACT ON QOL

Impact of a Parastomal Bulge on Quality of Life – A Cross-sectional Study of Patients From the Danish Stoma Database

Marianne Krogsgaard, MHS,\*†⊠ Torquil Watt, DMSc,‡ Anne K. Danielsen, PhD,†
Tobias Wirenfeldt Klausen, MSc,§ Anders Vinther, PhD,¶ Ismail Gögenur, DMSc,||
and Thordis Thomsen, PhD\*\*

**TABLE 2.** Mean and Adjusted Mean Differences in Health-related Quality of Life (HRQoL) Scores Between Patients With and Without a Self-reported Parastomal Bulge

| Scale/Subscale             | Bulge $(n = 693)$ | No Bulge $(n = 565)$ | Linear Regression <sup>†</sup> Ref. No Bulge | Effect Size           |
|----------------------------|-------------------|----------------------|--|-----------------------|
| SF-36                      | Mean (SD)         | Mean (SD)            | Adjusted Mean Difference (95% CI)            | Cohens d <sup>‡</sup> |
| Physical Functioning       | 65 (28)           | 72 (30)              | -5 (-8; -2)**                                | 0.17                  |
| Role-Physical              | 57 (34)           | 67 (38)              | $-8 (-12; -4)^{***}$                         | 0.25                  |
| Bodily Pain                | 72 (29)           | 75 (29)              | $-7(-10; -3)^{***}$                          | 0.23                  |
| General Health             | _ 56 (24)         | _ 60 (26)            | 6 (-9; -3)*** _                              | 0.23                  |
| Vitality                   | 54 (25)           | 59 (25)              | $-7(-10; -4)^{***}$                          | 0.28                  |
| Social Functioning         | 78 (28)           | 82 (20)              | 1 -4 **                                      | 0.26                  |
| Role-Emotional             | 66 (33)           | 74 (22)              | -5 ( 9: -1)                                  | 0.16                  |
| Mental Health              | 72 (22)           | 74<br>7. 20          | 4/-7; 29 *                                   | 0.21                  |
| SF-3 cummary scores        |                   |                      |  |                       |
| Physical Component summary | 46 (10)           | 48 (11)              | -3 (-4; -1)***                               | 0.26                  |
| Mental Component summary   | 48 (12)           | 50 (11)              | $-2(-4;-1)^{***}$                            | 0.21                  |
| Stoma-QOL summary score    | 62 (23)           | 70 (20)              | -9 (-12; -7)***                              | 0.44                  |

**TABLE 3.** Mean and Adjusted Mean Differences in Health-related Quality of Life (HRQoL) Among Patients With and Without a Parastomal Bulge, Presented Separately for Patients With an Underlying Malignant or Benign Diagnosis

|                            |  | Malignant                     | Diagnosis                                       |  | Benign o                | diagnosis                                       |   |  |
|----------------------------|--|-------------------------------|---|--|-------------------------|---|---|--|
| Scale/Subscale             | $\begin{array}{c} Bulge \\ n = 417^{\ddagger} \end{array}$ | No Bulge $n = 300^{\ddagger}$ | Linear Regression <sup>¶</sup><br>Ref. No Bulge | $\begin{array}{c} Bulge \\ n=276^{\S} \end{array}$ | No Bulge $n = 265^{\S}$ | Linear Regression <sup>¶</sup><br>Ref. No Bulge | Interaction, Bulging<br>Status and Diagnosis <sup>†</sup> |  |
| SF-36                      | Mean<br>(SD)   | Mean<br>(SD)                  | Adjusted Mean<br>Difference (95 % CI)           | Mean<br>(SD)                                       | Mean<br>(SD)            | Adjusted Mean<br>Difference (95% CI)            | P-value   |  |
| Physical Functioning       | 69 (26)  | 74 (28)                       | -4 (-8; 0)                                      | 59 (30)  | 71 (30)                 | -7 (-12; -2)**                                  | 0.407   |  |
| Role-Physical              | 61 (32)  | 70 (34)                       | $-7 (-12; -2)^{**}$                             | 51 (35)  | 64 (34)                 | $-11 (-17; -4)^{**}$                            | 0.600   |  |
| Bodily Pain                | 77 (26)  | 80 (28                        | -3(-8;1)  | 64 (31)  | 70 (29)                 | $-1$ $(-15; -5)^{***}$                          | 0.087   |  |
| General Health             | d (24)   | 65 (24                        | -5(-9;-1)**                                     | 49 (24)  | 54 (27)                 | (-12; 2)**                                      | 0.715   |  |
| Vitali y                   | 5 (13)   | 63 (24                        | - <i>((=)</i> - <i>(*</i>                       | 1 (2.  | 55 (25)                 | $-1 \left(-15 - 6\right)^{-**}$                 | 0.131   |  |
| Social Functioning         | <b>9</b> ( <b>1</b> 6)                                     | 85 (25                        | - <del>1 (=7-</del> 1                           | 1 (30  | 79 (27)                 | $-1/(-18:-7)^{**}$                              | 0. 9*   |  |
| Role-Emotional             | 69 (31)  | 75 (32)                       | $-4 \left( j; 1 \right)$                        | 62-61  | 72 (32)                 | (-13; -)  | 0.532   |  |
| Ment. Health               | 76 (20)  | 77 (20)                       | -2(-5;2)  | (6.3)  | 73 (20)                 | $-8 (-12; -4)^{***}$                            | 0.011*  |  |
| SF-36 summary scores       |  |                               |   |  |                         |   |   |  |
| Physical Component summary | 47 (9)   | 50 (10)                       | $-2(-4;-1)^{**}$                                | 43 (10)  | 46 (11)                 | $-3 (-5; -1)^{**}$                              | 0.581   |  |
| Mental Component summary   | 50 (11)  | 51 (11)                       | -1(-3;1)  | 45 (13)  | 48 (11)                 | $-4 (-7; -2)^{***}$                             | 0.038*  |  |
| Stoma-QOL summary score    | 64 (23)  | 73 (20)                       | $-9 (-12; -5)^{***}$                            | 58 (23)  | 66 (21)                 | $-10 (-13; -6)^{***}$                           | 0.529   |  |

**TABLE 4.** Mean and Adjusted Mean Differences in Health-related Quality of Life (HRQoL) Among Patients With and Without a Parastomal Bulge, Presented Separately for Patients With a Colostomy or an Ileostomy

|                            | Colostomy   |                               |                                      | Ileostomy  |                      |                                      |   |  |
|----------------------------|---|-------------------------------|--------------------------------------|--|----------------------|--------------------------------------|---|--|
| Scale/Subscale             | $\begin{array}{c} \text{Bulge} \\ n = 533^{\ddagger} \end{array}$ | No Bulge $n = 315^{\ddagger}$ | Linear Regression¶<br>Ref No Bulge   | $\begin{array}{c} Bulge \\ n = 160^{\S} \end{array}$ | No Bulge<br>n = 250§ | Linear Regression¶<br>Ref. No Bulge  | Interaction, Bulging Status<br>and Type of Stoma <sup>†</sup> |  |
| SF-36                      | Mean<br>(SD)  | Mean<br>(SD)                  | Adjusted Mean<br>Difference (95% CI) | Mean<br>(SD)   | Mean<br>(SD)         | Adjusted Mean<br>Difference (95% CI) | P-value   |  |
| Physical Function          | (20)  | 70 (32)                       | <b>2</b> (− <b>7</b> 1)              | 64 (28)  | 75 (26)              | -9 (-14; -4)***                      | 0.110   |  |
| Role-Physical              | 5. (3:  | 67 (35)                       | $6(-10; -1)^*$                       | 51 (25)  | 67 (32)              | 12 (-20: 6)***                       | 0.214   |  |
| Bodil Pain                 | 74 (2:1)  | 77 (29)                       | $-5(-9)^*$                           | 6 (31)   | 73 (28)              | -10 ( -1 , -: ***                    | 0.063   |  |
| General Health             | 5. (3.<br>74 (2.<br>5 (2.   | 63 (26)                       | $-4(-8 - )^*$                        | 4 (26)   | 56 ( 6)              | <b>−9 / -1</b> ; <b>−3</b> **        | 0.248   |  |
| Viteli v                   | 57 (2 <del>+)</del>   | 01 (25)                       | $-5(-8, -1)^{**}$                    | 48 (=0)  | 57 (24)              | -12 (-17; -7)***                     | 0.095   |  |
| Socia Functioning          | 80 (27)   | 83 (27)                       | -3(-7;1)                             | 69 (31)  | 81 (26)              | $-14(-20; -8)^{***}$                 | 0.005**   |  |
| Role-Emotional             | 68 (33)   | 73 (34)                       | -3(-8; 2)                            | 63 (35)  | 74 (30)              | $-10(-16, -3)^{**}$                  | 0.219   |  |
| Mental Health              | 73 (21)   | 75 (20)                       | -2(-5;1)                             | 67 (24)  | 74 (20)              | $-9(-14; -5)^{***}$                  | 0.017*  |  |
| SF-36 summary scores       |   |                               |                                      |  |                      |                                      |   |  |
| Physical Component summary | 46 (9)  | 48 (11)                       | $-2(-3; -0.3)^*$                     | 43 (10)  | 48 (10)              | $-4 (-6; -2)^{***}$                  | 0.141   |  |
| Mental Component summary   | 48 (11)   | 50 (11)                       | -1 (-3; 1)                           | 45 (13)  | 49 (11)              | $-5(-7; -3)^{***}$                   | 0.034*  |  |
| Stoma-QOL summary score    | 64 (22)   | 71 (21)                       | $-7(-11; -4)^{***}$                  | 55 (23)  | 68 (20)              | $-13(-17; -9)^{***}$                 | 0.095   |  |

TABLE 5. Mean and Adjusted Mean Differences in Health-related Quality of Life (HRQoL) Scores Between Patients With Large (>10 cm) and a Small (< 10 cm) Self-reported Parastomal Bulge

| Scale/Subscale             | Large Bulge $(n = 296)$ | Small Bulge $(n = 397)$      | Linear Regression <sup>†</sup> Ref. Small Bulge | Effect Size           |
|----------------------------|-------------------------|------------------------------|---|-----------------------|
| SF-36                      | Mean (SD)               | Mean (SD)                    | Adjusted Mean Difference (95% CI)               | Cohens d <sup>‡</sup> |
| Physical Functioning       | 60 (28)                 | 69 (27)                      | -7 (-11; -3)**                                  | 0.24                  |
| Role-Physical              | 51 (34)                 | 61 (33)                      | -9 (-14; -4)***                                 | 0.27                  |
| Bodily Pain                | 69 (29)                 | 74 (28)                      | $-8(-12; -3)^{**}$                              | 0.26                  |
| General Health             | 52 (24)                 | 60 (24)                      | -11; -11*                                       | 0.21                  |
| Vitality                   | 51 (25)                 | 57 (4)                       | −7 ( <del></del>                                | .30                   |
| Social Functioning         | 75 (29)                 | 80 (7)                       | -(-10; -1)                                      | .21                   |
| Role-Imotional             | 30 (35)                 | $\mathcal{L}(\mathcal{L}_1)$ | -8(-14; -3)                                     | 0.26                  |
| Mental Health              | 68 (24)                 | 75 (20)                      | $-7(-10; -4)^{***}$                             | 0.33                  |
| SF-36 summary scores       | , ,                     | , ,                          | , , ,   |                       |
| Physical Component summary | 44 (10)                 | 47 (9)                       | $-3(-4;-1)^{***}$                               | 0.30                  |
| Mental Component summary   | 46 (12)                 | 49 (11)                      | $-4(-5; -2)^{***}$                              | 0.31                  |
| Stoma-QOL summary score    | 58 (23)                 | 64 (22)                      | $-8(-11; -4)^{***}$                             | 0.34                  |

# Why do patients get parastomal hernias?

## RISK FACTORS - PATIENT & TECHNICAL

#### Patient factors:

Age

Malnutrition

Obesity

**Diabetes** 

Connective tissue disorders

Wound infection

**Smoking** 

Previous laparotomies

Previous herniae

Steroids / immunosuppression

Benign v malignant disease

↑ IAP – COPD / BPH / ascites

#### Technical factors:

**Emergency surgery** 

Stoma site (rectus)

Trans or extraperitoneal

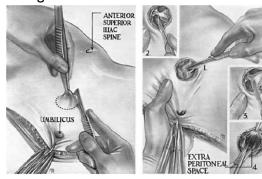
Fixation to fascia

Closure of lateral space

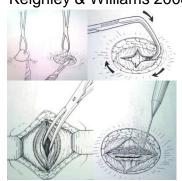
Laparoscopic surgery?

Avoidance of stoma

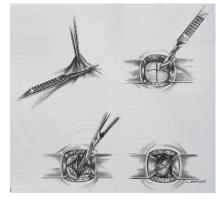
#### Goligher 1958



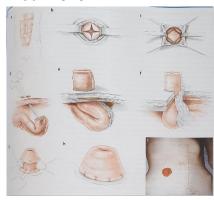
Keighley & Williams 2008



#### Corman 2013



#### Beck 2019



Trephine size (shape?)

Prophylactic mesh

## MAKING A STOMA

### European Hernia Society guidelines on prevention and treatment of parastomal hernias

a. Extraperitoneal versus transperitoneal stoma construction

**Statement:** There is insufficient evidence on the comparative risk of parastomal hernia development after construction of a stoma via the extraperitoneal or the transperitoneal route.

**Recommendation:** No recommendation can be made in preference of stoma construction through the extraperitoneal over the transperitoneal route.

Quality of evidence: ⊠□□□ Strength of recommendation: No

b. Stoma construction at a lateral pararectus location versus a transrectus location

**Statement:** There is insufficient evidence on the comparative risk of parastomal hernia development after construction of the stoma at a lateral pararectus location or a transrectus location.

**Recommendation:** No recommendation can be made in preference of stoma construction at a lateral pararectus location over a transrectus location.

Quality of evidence:⊠□□□

Strength of recommendation: No

c. Size of the fascial aperture

**Statement:** There is insufficient evidence on the ideal size of the fascial aperture when constructing a stoma.

**Recommendation:** We suggest keeping the size of the fascial aperture as small as possible to allow passage of the intestine through the abdominal wall without causing ischemia.

*Quality of evidence:* ⊠□□□

Strength of recommendation: Weak

Prevention and treatment of parastomal hernia: a position statement on behalf of the Association of Coloproctology of Great Britain and Ireland

#### Statement

- 1 There is insufficient evidence to ascertain whether the extraperitoneal route of stoma construction reduces PSH rate in comparison to the transperitoneal route.
- 2 There is insufficient evidence to support the assertion of lower PSH rates with stoma trephines within the rectus sheath compared to those lateral to the rectus sheath.
- **3** There is insufficient evidence to advocate LRAPS in preference to a rectus abdominis muscle splitting stoma trephine.
- 4 There is currently insufficient evidence to support the use of any particular shape of incision (either circular or cruciate) in terms of reducing the rate of PSH.
- **5** There is insufficient evidence to support claims regarding the absolute optimal size of the stomal trephine; however, it is intuitive to use the smallest trephine without causing bowel ischaemia.

Quality of evidence

Low

Strength of recommendation

None

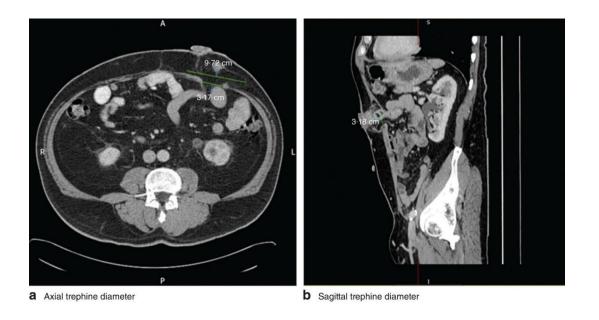
## TREPHINE OVER TIME

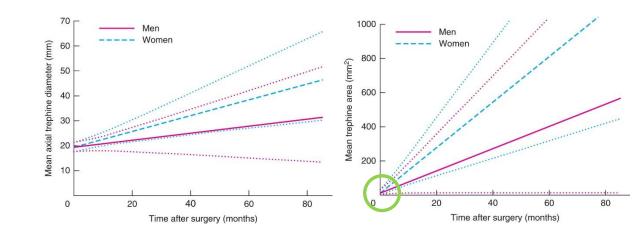
#### Radiological progression of end colostomy trephine diameter

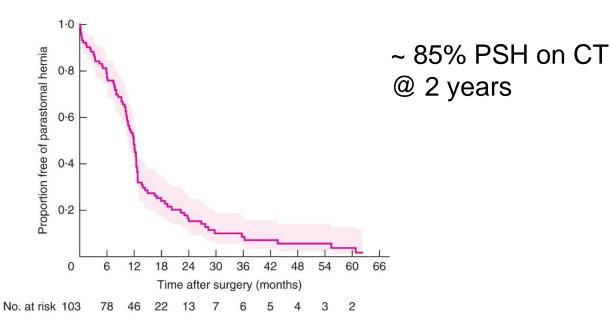
and area K. K. Ho<sup>1</sup>, T. Economou<sup>2</sup>, N. J. Smart<sup>3</sup> and I. R. Daniels<sup>3</sup>

I: 10.1002/bjs5.50109

- Trephine larger in ♀ than ♂
- Rate of change over time 2 > 3 too.
- Shape & location of trephine not significant







## STUDY AIMS



 PSH = incisional hernia related to a stoma



 Incidence of symptomatic & radiological PSH min 2 yr. FU



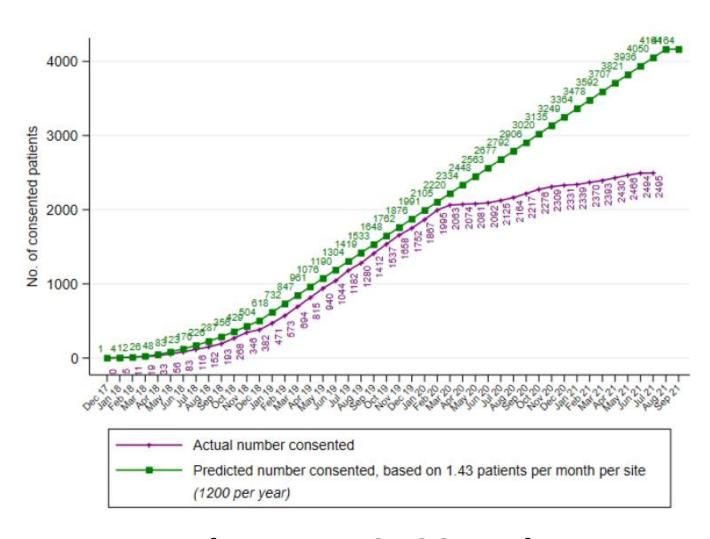
 Effects of key technical surgical steps during stoma formation



## COVID CHANGES







**Recruitment = 2498 patients** 



- This is an OBSERVATIONAL Study cumulative time exposed to risk is the key factor (person years)
- 2498 recruited, but follow up for longer....
- ~£250k NIHR HTA extension awarded



## FOLLOW UP ONGOING

**1**ST Sept **2022** 

## Cohort



\_.\_. .. .\_\_. ... . ... \_... ... ... . ... . ... \_... ... . ...

|   |                | Tumour (n=1693) | Inflammatory Bowel<br>Disease (n=285) | Functional & Diverticular (n=385) | Overall (n=2363) |
|---|----------------|-----------------|---------------------------------------|-----------------------------------|------------------|
| Age (mean; SD)                                      |                | 66.9 (11.5)     | 45.5 (16.6)                           | 59.1 (16.0)                       | 63.1 (14.9)      |
| Sex; n (%)  | Male           | 1063/1693 (63%) | 152/285 (53%)                         | 148/385 (38%)                     | 1363/2363 (58%)  |
|   | Female         | 630/1693 (37%)  | 133/285 (47%)                         | 237/385 (62%)                     | 1000/2363 (42%)  |
| Smoking status; n (%)                               | Current smoker | 155/1689 (9%)   | 28/284 (10%)                          | 73/384 (19%)                      | 256/2357 (11%)   |
| Diabetes type; n (%)                                | Type 1         | 17/241 (7%)     | 5/23 (22%)                            | 5/46 (11%)                        | 27/310 (9%)      |
|   | Type 2         | 224/241 (93%)   | 18/23 (78%)                           | 41/46 (89%)                       | 283/310 (91%)    |
| Therapeutic oral or injected corticosteroids; n (%) | Yes            | 46/1689 (3%)    | 113/284 (40%)                         | 29/384 (8%)                       | 188/2357 (8%)    |
| Immuno-suppressive medication; n (%)                | Yes            | 15/1689 (1%)    | 36/283 (13%)                          | 7/384 (2%)                        | 58/2356 (2%)     |
| Disease modifying agents; n (%)                     | Yes            | 33/1689 (2%)    | 120/283 (42%)                         | 20/384 (5%)                       | 173/2356 (7%)    |
| Previous abdominal surgery; n (%)                   |                | 430/1689 (25%)  | 0/13 (0%)                             | 0/24 (0%)                         | 678/2357 (29%)   |
| Abdominal wall hernia; n (%)                        |                | 131/1689 (8%)   | 15/284 (5%)                           | 34/384 (9%)                       | 180/2357 (8%)    |
| Any muscular or connective tissue disorder; n (%)   |                | 172/1689 (10%)  | 39/284 (14%)                          | 82/384 (21%)                      | 293/2357 (12%)   |
| Frailty score; median (IQR)                         |                | 2 (2, 3)        | 3 (2, 3)                              | 3 (2, 4)                          | 2 (2, 3)         |

## Cohort



|   |              | Tumour (n=1693) | Inflammatory Bowel<br>Disease (n=285) | Functional & Diverticular (n=385) | Overall (n=2363) |
|---|--------------|-----------------|---------------------------------------|-----------------------------------|------------------|
| Small bowel resection; n (%)                              |              | 19/1693 (1%)    | 10/285 (4%)                           | 8/385 (2%)                        | 37/2363 (2%)     |
| Colectomy - left; n (%)                                   |              | 496/169 (29%)   | 5/285 (2%)                            | 48/385 (12%)                      | 549/2363 (23%)   |
| Colectomy - right; n (%)                                  |              | 37/1693 (2%)    | 24/285 (8%)                           | 8/385 (2%)                        | 69/2363 (3%)     |
| Colectomy - subtotal or panproctocolectomy; n (%)         |              | 84/1693 (5%)    | 201/285 (71%)                         | 20/385 (5%)                       | 305/2363 (13%)   |
| Hartmann's procedure; n (%)                               |              | 203/1693 (12%)  | 4/285 (1%)                            | 80/385 (21%)                      | 287/2363 (12%)   |
| Abdominoperineal excision / posterior exenteration; n (%) |              | 523/1693 (31%)  | 7/285 (2%)                            | 3/385 (1%)                        | 533/2363 (23%)   |
| Stoma formation; n (%)                                    |              | 585/1693 (35%)  | 87/285 (31%)                          | 251/385 (65%)                     | 923/2363 (39%)   |
| Other; n (%)  |              | 234/1693 (14%)  | 35/285 (12%)                          | 73/385 (19%)                      | 290/2363 (12%)   |
|   |              |                 |                                       |                                   |                  |
| Intended type of access used; n (%)                       | SILS         | 3/1640 (0%)     | 9/282 (3%)                            | 3/379 (1%)                        | 15/2301 (1%)     |
|   | Laparoscopic | 1081/1640 (66%) | 210/282 (74%)                         | 254/379 (67%)                     | 1545/2301 (67%)  |
|   | Robotic      | 125/1640 (8%)   | 3/282 (1%)                            | 2/379 (1%)                        | 130/2301 (6%)    |
|   | Open         | 412/1640 (25%)  | 58/282 (21%)                          | 111/379 (29%)                     | 581/2301 (25%)   |
|   | Trephine     | 19/1640 (1%)    | 2/282 (1%)                            | 9/379 (2%)                        | 30/2301 (1%)     |

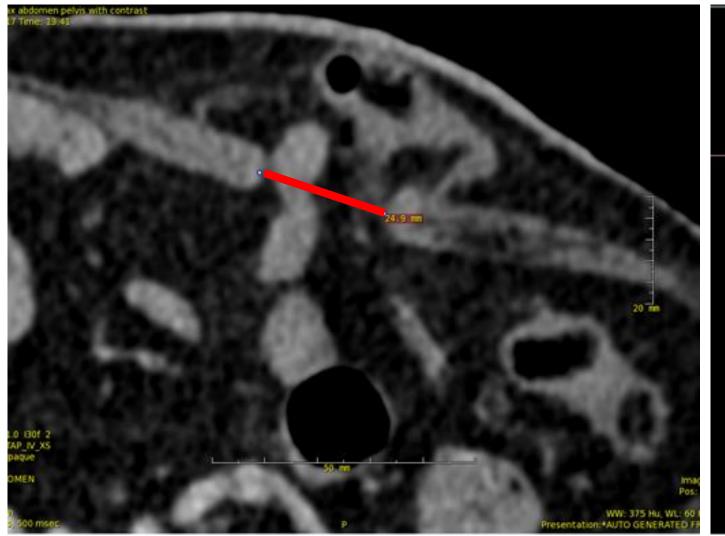
## Cohort



|  |                  | Tumour (n=1693) | Inflammatory Bowel<br>Disease (n=285) | Functional & Diverticular (n=385) | Overall (n=2363) |
|--|------------------|-----------------|---------------------------------------|-----------------------------------|------------------|
| Route of stoma; n (%)                            | Trans-peritoneal | 1322/1357 (97%) | 224/228 (98%)                         | 299/305 (98%)                     | 1845/1890 (98%)  |
|  | Extra-peritoneal | 35/1357 (3%)    | 4/228 (2%)                            | 6/305 (2%)                        | 45/1890 (2%)     |
| Ileostomy: type of stoma formed; n (%)           | End              | 110/608 (18%)   | 215/246 (87%)                         | 29/110 (26%)                      | 354/964 (37%)    |
|  | Loop             | 486/608 (80%)   | 25/246 (10%)                          | 77/110 (70%)                      | 588/964 (61%)    |
|  | Other or missing | 12/608 (2%)     | 6/246 (2%)                            | 4/110 (4%)                        | 22/964 (2%)      |
| Colostomy: type of stoma formed; n (%)           | End              | 839/1014 (83%)  | 15/32 (47%)                           | 180/267 (67%)                     | 1034/1313 (79%)  |
|  | Loop             | 166/1014 (16%)  | 16/32 (50%)                           | 64/267 (24%)                      | 246/1313 (19%)   |
|  | Other or missing | 9/1014 (1%)     | 1/32 (0%)                             | 23/267 (9%)                       | 33/1313 (2%)     |
| Mesh used to reinforce the stoma trephine; n (%) |                  | 51/1617 (3%)    | 2/281 (1%)                            | 4/375 (1%)                        | 57/2273 (3%)     |

## CT SCAN MEASUREMENTS

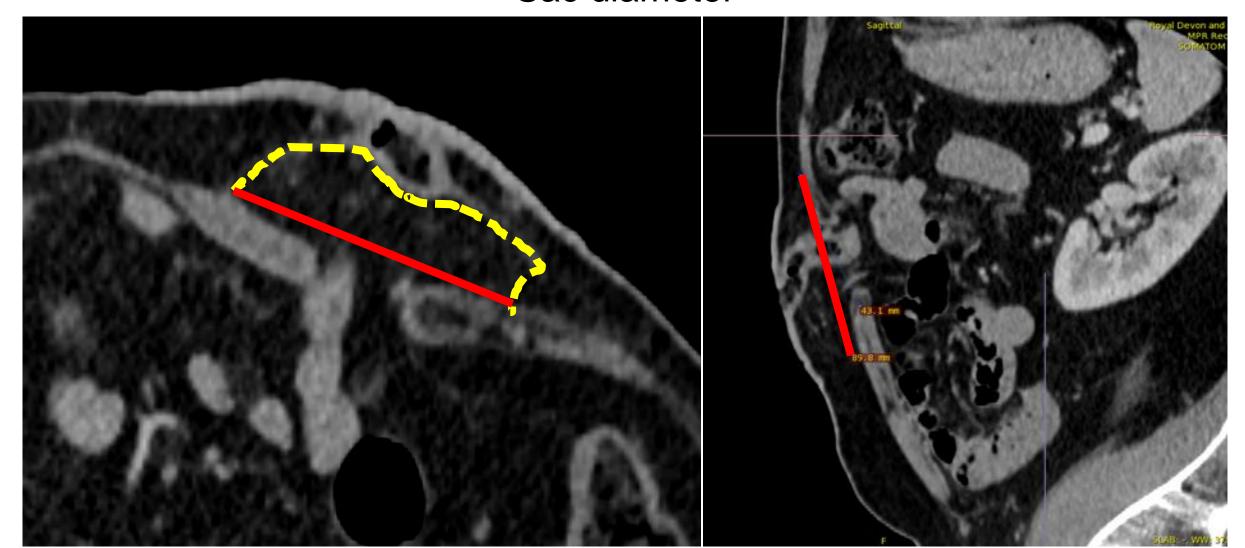
## Trephine diameter





## CT SCAN MEASUREMENTS

### Sac diameter

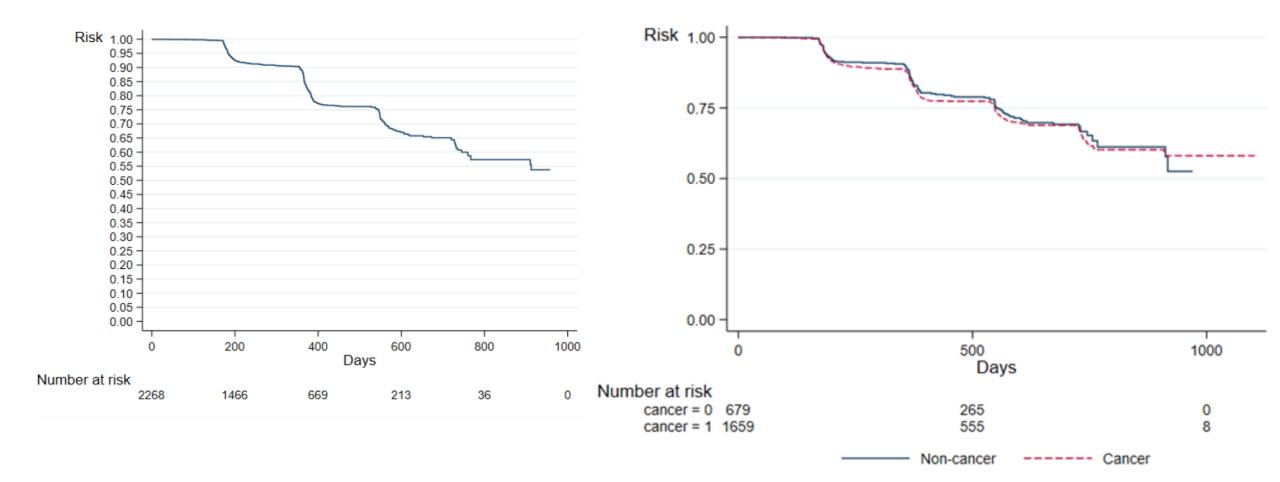




## What we know so far...

Time to patient reported PSH development

Time to reported PSH by cancer/non-cancer



## Mesh use is low (<3%)



#### Proposed comparisons of surgical technique items for primary outcome analyses

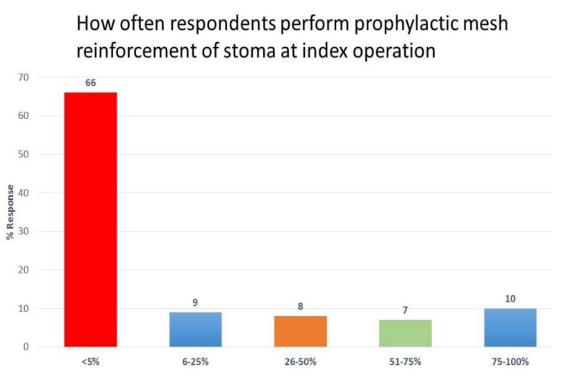
| Surgical technique item                   | Comparison                               | Percentage  | Ratio    | Excluded |
|---|--|-------------|----------|----------|
| Intended type of access used; n (%)       | Minimally invasive<br>Open               | 72%<br>26%  | 1 : 1.27 | 2%       |
| Type of stoma formed; n (%)               | End<br>Loop                              | 58%<br>40%  | 1 : 1.45 | 2%       |
| Bowel used to form stoma; n (%)           | Colon (descending/sigmoid)<br>Ileum      | 53%<br>45%  | 1 : 1.18 | 2%       |
| Stoma site pre-marked; n (%)              | Preserved with pen Preserved with suture | 74%<br>24%  | 1:3.08   | 2%       |
| Anterior sheath: Shape of incision; n (%) | Cruciate or linear<br>Circular           | 89%<br>11%  | 1 : 8.09 | 1%       |
| Posterior sheath: incision shape; n (%)   | Linear (horizontal/vertical)<br>Cruciate | 52%<br>42%  | 1 : 1.24 | 5%       |
| Location of trephine; n (%)               | Other than port site<br>At port site     | 44%<br>28%  | 1 : 1.57 | 27%      |
| Sutures used to buttress incision; n (%)  | No<br>Yes                                | 90%<br>10%  | 1:10.0   | 0%       |
| Stoma trephine = extraction site; n (%)   | No<br>Yes                                | 93%)<br>7%) | 1 : 13.3 | 0%       |
| Closure of deep layer; n (%)              | Large bite closure<br>Small bite closure | 41%<br>28%  | 1 : 1.46 | 31%      |

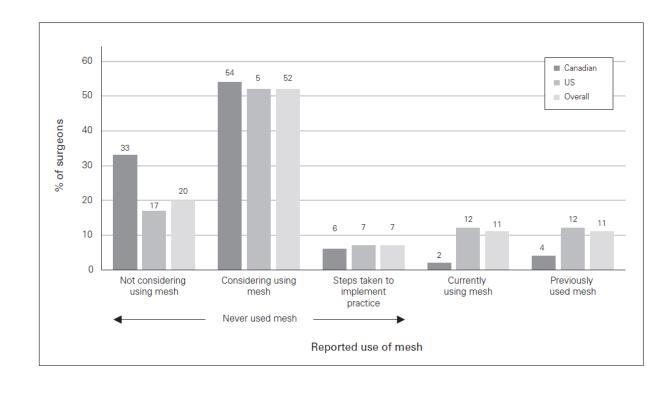
## MESH USE NOT WIDESPREAD

A survey on practices for parastomal hernia prevention and repair among ESCP surgeons

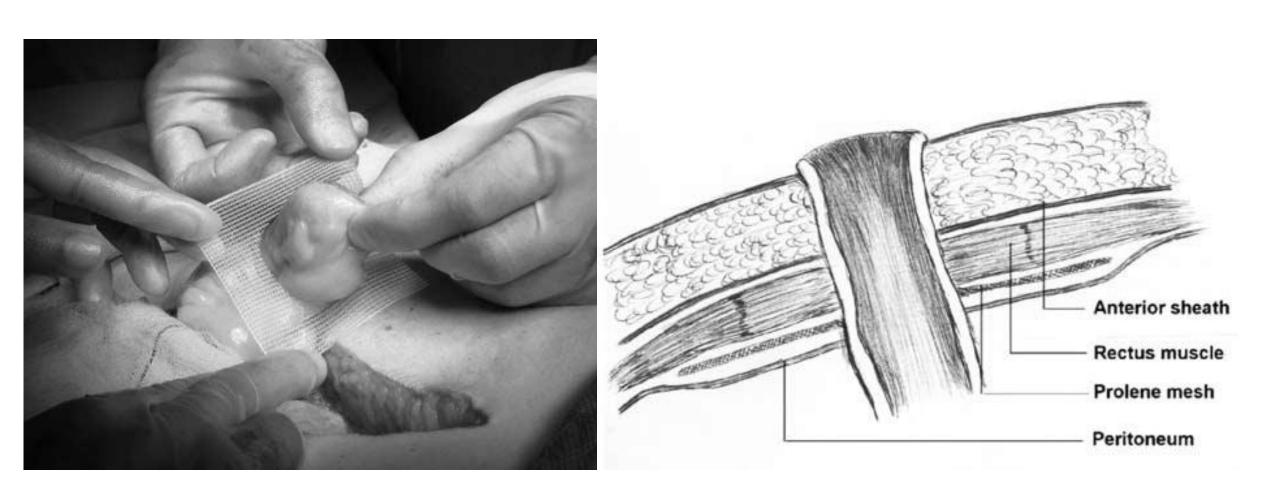
Hernia https://doi.org/10.1007/s10029-019-01921-z

Do North American colorectal surgeons use mesh to prevent parastomal hernia? A survey of current attitudes and practice Can J Surg, Vol. 62, No. 6, December 2019





## PROPHYLACTIC MESH



## PROPHYLACTIC MESH

European Hernia Society guidelines on prevention and treatment of parastomal hernias

Does the use of a prophylactic mesh during stoma construction reduce the incidence of parastomal hernias?

**Statements:** High quality evidence supports the use of a prophylactic mesh during construction of a permanent end colostomy in elective surgery in reducing the incidence of parastomal hernia development.

**Recommendation:** It is recommended to use a prophylactic synthetic non-absorbable mesh when constructing an elective permenent end colostomy to reduce the parastomal hernia rate.

Quality of evidence: 🗷 🗷

Strength of recommendation: Strong

**Recommendation:** No recommendation to use a prophylactic mesh can be made for ileostomies or ileal conduit stomas, nor for the use of synthetic absorbable or biological meshes.

Quality of evidence: ☒☒☐☐

Strength of recommendation: No

Prevention and treatment of parastomal hernia: a position statement on behalf of the Association of Coloproctology of Great Britain and Ireland

#### Statement

The use of non-absorbable synthetic mesh may reduce the incidence of PSH in patients who have permanent end colostomy formation for cancer only during elective surgery.

There is insufficient evidence regarding

- 1 optimal mesh position within the abdominal wall (retromuscular *vs* intraperitoneal on-lay mesh)
- 2 use of biologic meshes
- 3 prophylactic mesh in emergency surgery
- 4 prophylactic mesh use for ileostomy/urostomy
- **5** indications for stoma other than cancer (e.g. inflammatory bowel disease/functional)
- 6 cost effectiveness
- 7 long-term data, although this is in progress. Results are expected in the next few years.

#### Recommendation

Prophylactic synthetic non-absorbable mesh may be used when constructing an elective permanent end colostomy for encer only to reduce the risk of PSH development.

Quality of evidence

Moderate

Strength of recommendation

Weak

## PROPHYLACTIC MESH

**Cochrane Database of Systematic Reviews** 

European Hernia Society guidelines on prevention and treatment

## Prosthetic mesh placement for the prevention of parastomal herniation

Cochrane Systematic Review - Intervention | Version published: 20 July 2018 | see what's new



Prevention and treatment of parastomal hernia: a position

Great Britain and Ireland

statement on behalf of the Association of Coloproctology of

#### **Quality of evidence**

of parastomal hernias

We found low-quality evidence avouring the insertion of a mesh into people having a stoma.

## GOLD STANDARD EVIDENCE

DOI: 10.1111/codi.15849

#### SYSTEMATIC REVIEW



Use of prophylactic mesh during initial stoma creation to prevent parastomal herniation: a systematic review and meta-analysis of randomised controlled trials

Syed Mohiuddin<sup>1</sup> | William Hollingworth<sup>1</sup> | Niroshini Rajaretnam<sup>2</sup> | Barnaby C. Reeves<sup>3</sup> | Neil J. Smart<sup>2</sup>

|  |                     | Mesh            | No I   | /lesh |                              |      |              |        |
|--|---------------------|-----------------|--------|-------|------------------------------|------|--------------|--------|
| Study                                  | Events              | Total           | Events | Total | Risk Ratio, M-H, Random      | RR   | 95% CI       | Weight |
| Brandsma 2017 [2]                      | 3                   | 67              | 16     | 66    | — <del></del>                | 0.18 | [0.06; 0.60] | 5.4%   |
| Correa Marinez 2021 [35]               | 23                  | 58              | 32     | 63    |                              | 0.78 | [0.52; 1.16] | 12.3%  |
| Fleshman 2014 [46]                     | 5                   | 49              | 7      | 53    | <del>-</del>                 | 0.77 | [0.26; 2.27] | 6.0%   |
| Hammond 2008 [47]                      | 0                   | 10              | 3      | 10    | *                            | 0.14 | [0.01; 2.44] | 1.3%   |
| Jänes 2009 [43]                        | 2                   | 27              | 20     | 27    |                              | 0.10 | [0.03; 0.39] | 4.5%   |
| Lambrecht 2015 [48]                    | 2                   | 32              | 12     | 26    |                              | 0.14 | [0.03; 0.55] | 4.3%   |
| López-Cano 2012 [49]                   | 9                   | 18              | 15     | 16    | <u> </u>                     | 0.53 | [0.33; 0.86] | 11.5%  |
| López-Cano 2016 [50]                   | 6                   | 24              | 18     | 28    |                              | 0.39 | [0.18; 0.82] | 8.7%   |
| Odensten 2019 [5]                      | 33                  | 99              | 36     | 99    | -                            | 0.92 | [0.63; 1.34] | 12.5%  |
| Prudhomme 2021 [36]                    | 30                  | 70              | 28     | 65    | <u> </u>                     | 0.99 | [0.67; 1.47] | 12.4%  |
| Serra-Aracil 2009 [51]                 | 6                   | 27              | 12     | 27    |                              | 0.50 | [0.22; 1.14] | 8.0%   |
| Târcoveanu 2014 [42]                   | 0                   | 20              | 6      | 22    | <u> </u>                     | 0.08 | [0.01; 1.41] | 1.4%   |
| Vierimaa 2015 [37]                     | 18                  | 35              | 17     | 32    | <u></u>                      | 0.97 | [0.61; 1.53] | 11.7%  |
| Total                                  | 137                 | 536             | 222    | 534   |                              | 0.54 | [0.39; 0.77] | 100.0% |
| Heterogeneity: $I^2 = 67\%$ , $\tau^2$ | $r^2 = 0.2080, \mu$ | <i>p</i> < 0.01 |        |       | 0.01 0.1 1 10 100            |      |              |        |
|  |                     |                 |        |       | Favours mesh Favours no mesh |      |              |        |

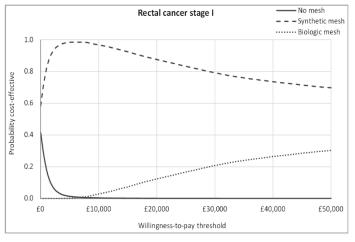
- Now 13 RCTs
- >16 meta-analyses
- No more studies needed
- What more evidence could you want?

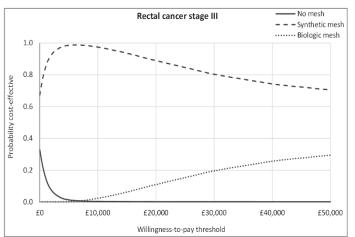


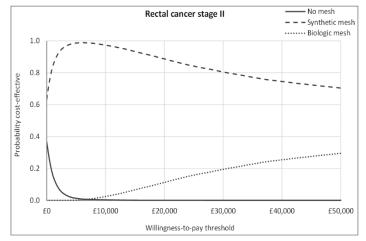
## SYNTHETIC MESH PROPHYLAXIS IS COST EFFECTIVE IN RECTAL CANCER PATIENTS

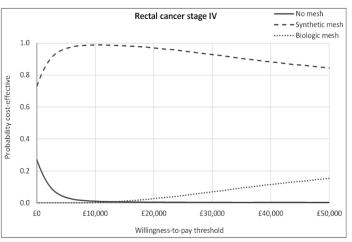
A semi-Markov model comparing the lifetime cost-effectiveness of mesh prophylaxis to prevent parastomal hernia in patients undergoing end colostomy creation for rectal cancer Colorectal Disease. 2021; DOI: 10.1111/codi.15848

Syed Mohiuddin<sup>1</sup> Barnaby C. Reeves<sup>2</sup> Neil J. Smart<sup>3</sup> William Hollingworth<sup>1</sup> On behalf of the CIPHER study group\*









# PROPHYLACTIC SYNTHETIC MESH SAVES \$\$

## Prophylactic mesh reinforcement of stomas: a cost-effectiveness meta-analysis of randomised controlled trials

J. M. Findlay<sup>1,2</sup> · C. P. J. Wood<sup>1</sup> · C. Cunningham<sup>1</sup>

Techniques in Coloproctology (2018) 22:265–270

| Table 3    Cost-effectiveness |      | Surgery alone        |           |  |  |  |  |
|-------------------------------|------|----------------------|-----------|--|--|--|--|
| Mesh NNT                      |      | Net cost per patient | t         |  |  |  |  |
|                               |      | Lowest               | Highest   |  |  |  |  |
| USD \$                        |      |                      |           |  |  |  |  |
| Synthetic                     | 11.1 | -1513.21             | -622.36   |  |  |  |  |
| Composite                     | 33.3 | -278.80 <b>-</b>     | +468.00   |  |  |  |  |
| Biological                    | 20   | +792.85              | +2351.40  |  |  |  |  |
| GBP £                         |      |                      |           |  |  |  |  |
| Synthetic                     | 11.1 | -365.91              | +135.91 - |  |  |  |  |
| Composite                     | 33.3 | + 106.03             | +306.70   |  |  |  |  |
| Biological                    | 20   | + 983.6 -            | +2011.25  |  |  |  |  |

| Table 3 Cost-e   | ffectiveness S | urgery and stoma nurse | gery and stoma nurse & appliance costs |  |  |  |
|------------------|----------------|------------------------|--|--|--|--|
| Mesh             | NNT            | Net cost per patie     | ent                                    |  |  |  |
|                  |                | Lowest                 | Highest                                |  |  |  |
| Plus additive st | oma costs      |                        |  |  |  |  |
| USD \$           |                |                        |  |  |  |  |
| Synthetic        | 3.45           | -2138.58               | -1192.29                               |  |  |  |
| Composite        | 6.68           | -698.68                | +173.65                                |  |  |  |
| Biological       | 16.67          | +624.60                | +2233.45                               |  |  |  |
| GBP £            |                |                        |  |  |  |  |
| Synthetic        | 3.45           | -991.27                | -552.32                                |  |  |  |
| Composite        | 6.68           | -216.95                | +80.27                                 |  |  |  |
| Biological       | 16.67          | +854.18                | +1920.52                               |  |  |  |
|                  |                |                        |  |  |  |  |

#### COMPLICATIONS – MESH IS SAFE

Use of prophylactic mesh during initial stoma creation to prevent parastomal herniation: a systematic review and meta-analysis of randomised controlled trials

Syed Mohiuddin<sup>1</sup> | William Hollingworth<sup>1</sup> | Niroshini Rajaretnam<sup>2</sup> | Barnaby C. Reeves<sup>3</sup> | Neil J. Smart<sup>2</sup>

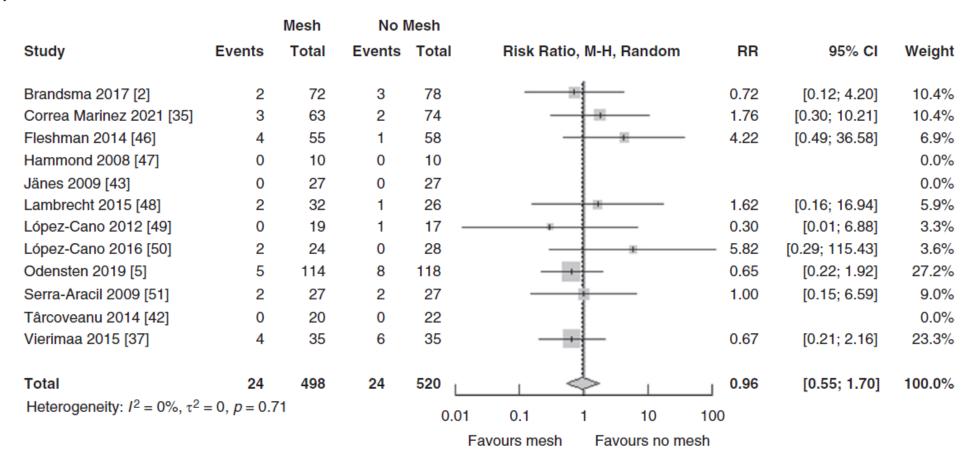


FIGURE 5 Forest plot of the risk of peristomal complications within 30 days of initial stoma creation

# What can we do about parastomal hernias?

## WATCHFUL WAITING

#### Commonest strategy

Risk vs benefit unknown
Increase in size over time?
More complex surgery if left?
When to operate?

12 year history of parastomal hernia & watchful waiting



Kind permission from Filip Muysoms, Ghent, 2017

# EXPERT STOMA CARE NURSING

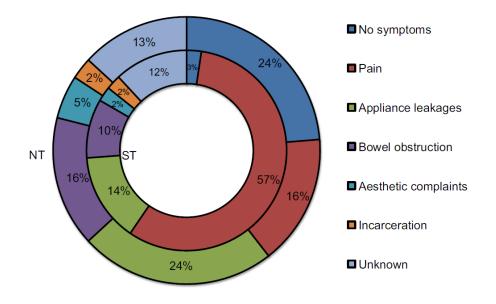


#### WATCHFUL WAITING

Non-operative treatment as a strategy for patients with parastomal hernia: a multicentre, retrospective cohort study

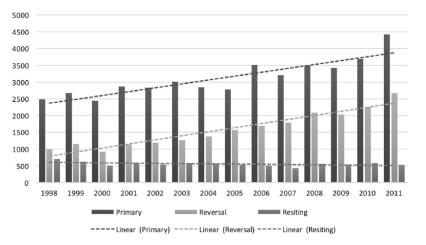
L. F. Kroese\*<sup>1</sup> D. P. V. Lambrichts\*<sup>1</sup>, J. Jeekel†, G. J. Kleinrensink†, A. G. Menon‡§, E. J. R. de Graaf§, W. A. Bemelman¶ and J. F. Lange\*‡§

- Watchful waiting in patients:
  - Older
  - **COPD**
  - Cancer
  - Fewer symptoms
- Cross over = 21%



#### PSH REPAIR - NO WALK IN THE PARK

#### Trends in parastomal hernia repair in the United States: a 14-y review JOURNAL OF SURGICAL RESEARCH • OCTOBER 2017 (218) 78-85



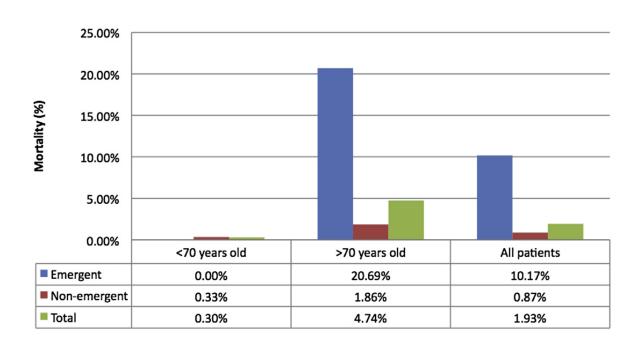
| Outcome                   | Overall  | Primary  | Reversal | Resiting | P value |
|---------------------------|----------|----------|----------|----------|---------|
| Mortality (%)             | 2.7      | 3.2      | 1.8      | 2.6      | < 0.01  |
| Complications (%)         |          |          |          |          |         |
| Acute respiratory failure | 3.2      | 3.5      | 2.5      | 3.5      | 0.01    |
| Cardiac complication      | 2.2      | 2.4      | 2.0      | 2        | 0.21    |
| Acute MI                  | 1.0      | 1.0      | 0.8      | 1.2      | 0.38    |
| CNS complication          | 0.1      | 0.2      | 0.1      | 0.1      | 0.28    |
| Acute cerebral accident   | 0.7      | 0.7      | 8.0      | 0.4      | 0.36    |
| UTI                       | 1.5      | 1.7      | 1.3      | 1.2      | 0.13    |
| Acute renal failure       | 5.8      | 6.3      | 4.9      | 5.1      | < 0.01  |
| Pulmonary embolism        | 0.7      | 0.7      | 0.5      | 0.8      | 0.21    |
| Acute DVT                 | 0.6      | 0.7      | 0.4      | 0.7      | 0.23    |
| Postop shock              | 0.3      | 0.3      | 0.3      | 0.4      | 0.96    |
| LOS, median days          | 6.3      | 6.1      | 6.5      | 6.7      | < 0.01  |
| Median cost of care       | \$14,533 | \$14,168 | \$15,016 | \$14,959 | < 0.01  |

#### http://dx.doi.org/10.1016/j.jamcollsurg.2014.01.054

Paracolostomy Hernia Repair: Who and When?

Zachary A Gregg, MD, Haisar E Dao, MD, Steven Schechter, MD, FACS, Nishit Shah, MD

#### NSQUIP 519 cases 2005-2008



# TALK ABOUT OUTCOME

- Recurrence is the key measure for surgeons
- But for patients....

Chronic pain

Mesh complications

Rigidity

Seroma

Infection

Erosion / Fistula

QoL & Function

Appliance fixation

Patient expectation



## BETTER AFTER SURGERY?

- Symptom threshold to intervene not defined
- Number of symptoms are all symptoms equal?
- Does 
   symptoms equate to improved QOL?

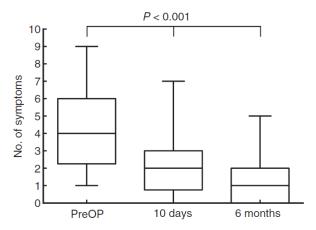


Figure 1 Median number of symptoms.

**Table 3** Prevalence of symptoms preoperatively, 10 days and 6 months after repair for parastomal hernia.

|   | Preoperative $N = 48 \text{ (\%)}$ | 10 days<br>N = 38 (%) | 6 months N = 35 (%) |
|---|------------------------------------|-----------------------|---------------------|
| Bearing-down sensation                      | 29/41 (71)                         | 5/35 (14)             | 3/31 (10)           |
| Pain  | 29/45 (64)                         | 23/35 (66)            | 4/31 (13)           |
| Difficulty finding properly fitting clothes | 24/42 (57)                         | 5/35 (14)             | 0/30(0)             |
| Difficulty with stomal appliance            | 25/45 (56)                         | 4/35 (11)             | 4/32 (13)           |
| Cosmetic complaints                         | 23/42 (55)                         | 4/35 (11)             | 1/32 (3)            |
| Activity limitation                         | 23/43 (54)                         | 12/35 (34)            | 1/31 (3)            |
| Leakage                                     | 20/43 (47)                         | 9/37 (24)             | 8/32 (25)           |
| Erratic action of the stoma                 | 18/42 (43)                         | 5/35 (14)             | 3/32 (9)            |
| Social restriction                          | 14/40 (35)                         | 3/35 (9)              | 2/32 (6)            |
| Skin problems                               | 12/40 (30)                         | 9/36 (25)             | 11/32 (34)          |

At postoperative day 10, 10 patients did not reply. At 6 months, one patient had died, three had recurrence and nine patients did not reply.

Krogsgaard et al CODI 2017

## BETTER AFTER SURGERY?

- Symptom threshold to intervene not defined
- Number of symptoms are all symptoms equal?
- Does 
   symptoms equate to improved QOL?

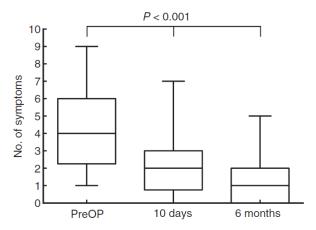


Figure 1 Median number of symptoms.

**Table 3** Prevalence of symptoms preoperatively, 10 days and 6 months after repair for parastomal hernia.

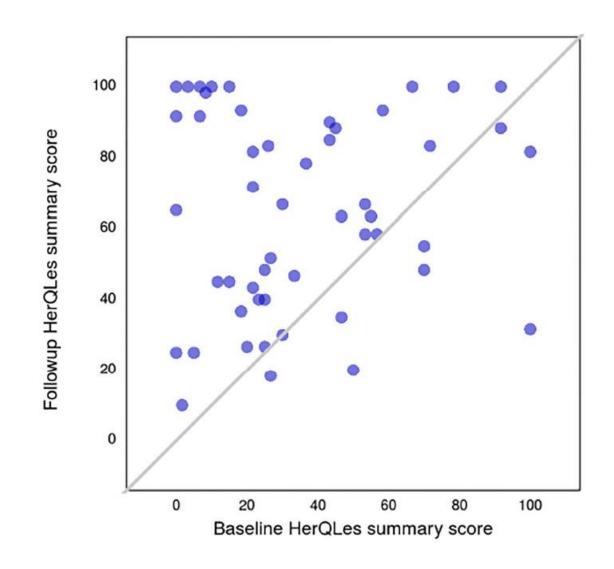
|   | Preoperative $N = 48 \text{ (\%)}$ | 10 days<br>N = 38 (%) | 6 months N = 35 (%) |
|---|------------------------------------|-----------------------|---------------------|
| Bearing-down sensation                      | 29/41 (71)                         | 5/35 (14)             | 3/31 (10)           |
| Pain  | 29/45 (64)                         | 23/35 (66)            | 4/31 (13)           |
| Difficulty finding properly fitting clothes | 24/42 (57)                         | 5/35 (14)             | 0/30(0)             |
| Difficulty with stomal appliance            | 25/45 (56)                         | 4/35 (11)             | 4/32 (13)           |
| Cosmetic complaints                         | 23/42 (55)                         | 4/35 (11)             | 1/32 (3)            |
| Activity limitation                         | 23/43 (54)                         | 12/35 (34)            | 1/31(3)             |
| Leakage                                     | 20/43 (47)                         | 9/37 (24)             | 8/32 (25)           |
| Erratic action of the stoma                 | 18/42 (43)                         | 5/35 (14)             | 3/32 (9)            |
| Social restriction                          | 14/40 (35)                         | 3/35 (9)              | 2/32 (6)            |
| Skin problems                               | 12/40 (30)                         | 9/36 (25)             | 11/32 (34)          |

At postoperative day 10, 10 patients did not reply. At 6 months, one patient had died, three had recurrence and nine patients did not reply.

Krogsgaard et al CODI 2017

# BETTER AFTER SURGERY?

- Data slowly accumulating
- AHSQC
- HerQLes
- 51 pre and post op at 6 or
   12 months follow up

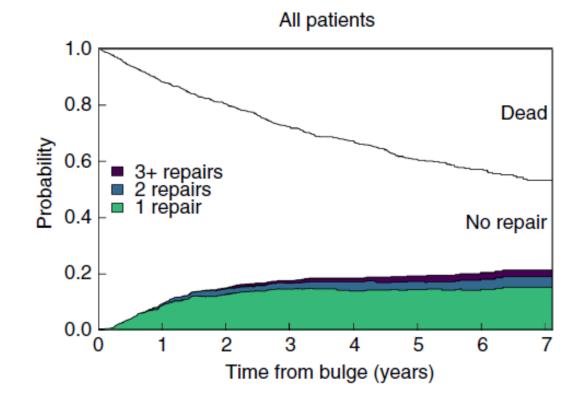


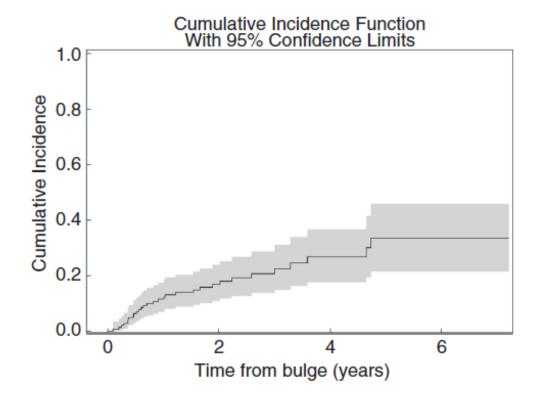
#### SYMPTOMS LEAD TO SURGERY

Surgical repair of parastomal bulging: a retrospective register-based study on prospectively collected data

Colorectal Disease © 2020 doi:10.1111/codi.15197

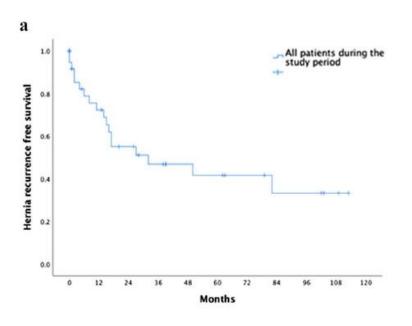
M. Krogsgaard\*'† (D), I. Gögenur‡, F. Helgstrand‡, R. M. Andersen\*'†, A. K. Danielsen†'§ (D), A. Vinther¶'\*\*, T. W. Klausen††, J. Hillingsø\*, B. M. Christensen\* and T. Thomsen§'‡‡

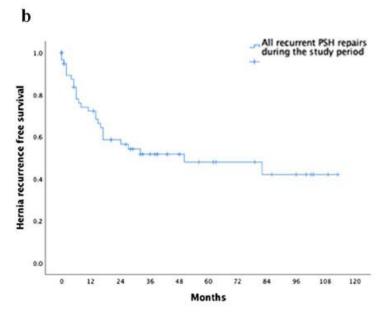


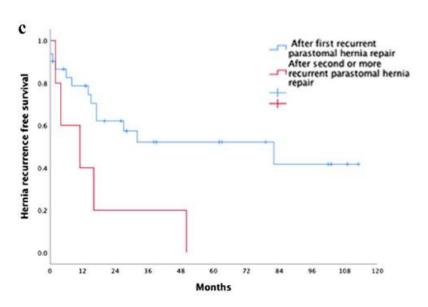


#### RECURRENT PSH OUTCOMES

Outcomes of surgically managed recurrent parastomal hernia: R. L. Harries <sup>1</sup> · I. R. Daniels <sup>1</sup> · N. J. Smart <sup>1</sup> the Sisyphean challenge of the hernia world https://doi.org/10.1007/s10029-020-02161-2







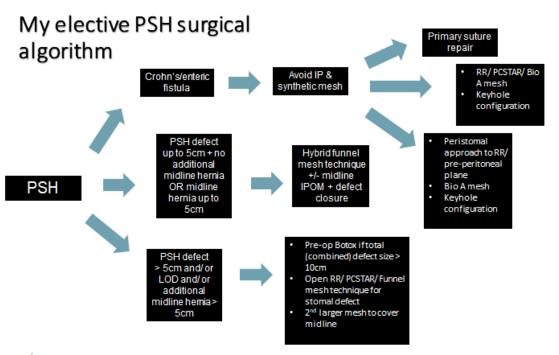
#### TAILORED APPROACH – DO EXPERTS AGREE?

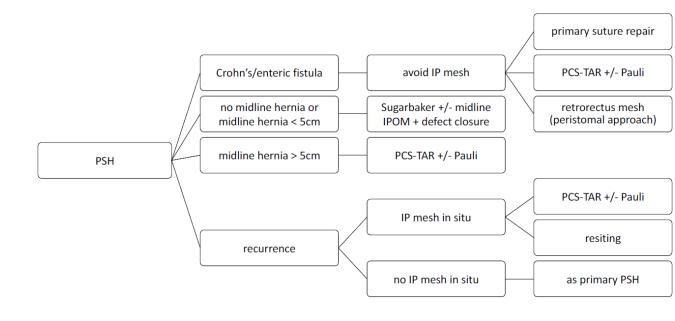


Toby Hammond

Akash Mehta



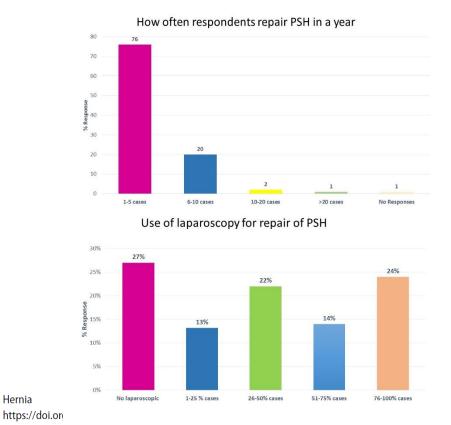




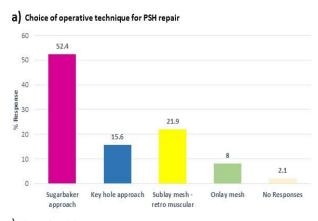
## PSH REPAIR – EU PERSPECTIVE

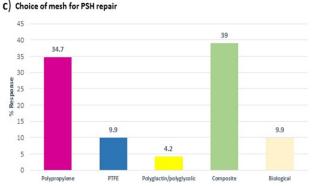
#### A survey on practices for parastomal hernia prevention and repair among ESCP surgeons

M. I. Aslam<sup>1,2</sup> · I. Rubio-Perez<sup>3</sup> · N. J. Smart<sup>4</sup> · B. Singh<sup>1,2</sup> · on behalf of European Society of Coloproctology **Education Committee** 



Hernia





# RELOCATION

#### Statement

Stoma relocation is associated with high rates of PSH development at the new stoma site and incisional hernia development at the site of previous incisions.

#### Recommendation

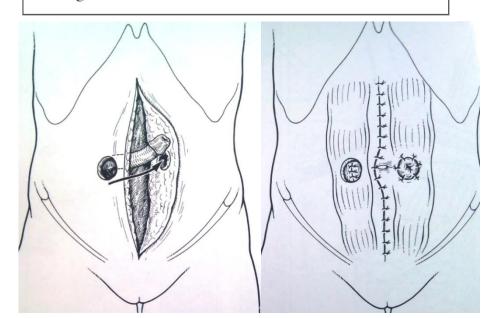
Stoma relocation as a treatment for PSH is not recommended.

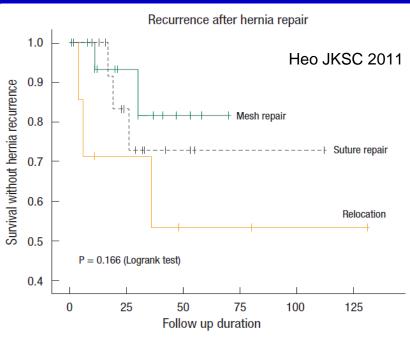
Quality of evidence

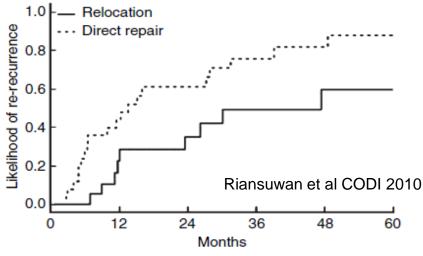
Low

Strength of recommendation

Strong







#### THE PATIENT VOICE – SUE BLACKWELL

#### **Surgical History**









2008 2010 2012 2012 2016 ????





Permacol Strattice - sublay Vycryl mesh - onlay Bard Parastomal Hernia Patch Covidien



Happy Sunday to me... back in the hotel NHS and the oncall consultant has given



When the deadline for the grant application is tomorrow and you are tethered to

a hospital bed (cos the catheter is at one end and the fluids all the way the other

side of the bed!) with the laptop balanced on your knees trying to make the final

0 4



4 hours in A&E and 7 hours in SAU before these happened... at least the Dr in SAU asked me what I wanted to do, and laughed at the referral from A&E "she's got a complex surgical history""what's she had done?""Well she's got an ileostomy..." think the rest was too much to grasp!





SueB @littlemissileo + 21 Nov 2017

Back home and back to a new surgery date. 21st December. Maybe Santa is bringing me a #parastomalhernia repair that will work. Hmmm, chances are about as much as Santa being real!



SueB @littlemissileo · Mar 16

When you have your back to work interview and your boss tells you that you'll be missing five days pay this month given SSP isn't paid for the first 3 days, and you've had two lots of time off in 4 weeks. #cantaffordgin



SueB @littlemissileo · Apr 1

I'm home! The last few weeks have been spectacularly awful. All I can say is that QoL after #parastomalhernia repair can be bloody awful, far worse than with a PSH. I have learnt the hard way that the decision I made in 2007 was the wrong one. #gladtobehome

○ 17 1 7

**SueB** @littlemissileo · Apr 23

Travel insurance when you have to declare 5 or more obstructions and AKI... £100+ single trip or £550+ for annual for Europe and £950+ for single trip or £1600+ for annual to include the USA...

Maybe add that to your #parastomalhernia repair consent forms!! 😥 😥



SueB @littlemissileo · May 24

Nothing like getting your payslip and seeing nearly £300 deducted thanks to the recent hotel NHS stay. That's why LOS matters in any #SBO PROM. I've had enough of being an adult, it sucks!





















































## PSH - THE PATIENT DILEMMA!

What are the expected outcomes? What are your outcomes for this Sx?

Will surgery improve or worsen QoL? For how long?

Is there a non-operative option?

What happens if we do nothing?

The balancing act...



Benefits/risks of mesh

How much worse would things be without mesh?

What type of mesh?
What's the long term data on outcomes?

Can I live with my symptoms?

#### PROPHER - ESCP COHORT STUDY

International cohort study of parastomal hernia repair and patient-level outcomes





#### Patient Reported Outcomes after Parastomal HErnia tReatment



Who

- Any patient >18
- Surgeon or SCN recruitment
- Operative intervention or watchful waiting



Surgeon

- Operative technique
- · 30 day outcomes







#### **Patient**

- Long term outcomes
- · Quality of life
- Satisfaction
- Decisional regret













## Who

#### Any patient with PSH having active management

- SCN or Surgeon recruitment
- > 18 years
- Bowel stoma

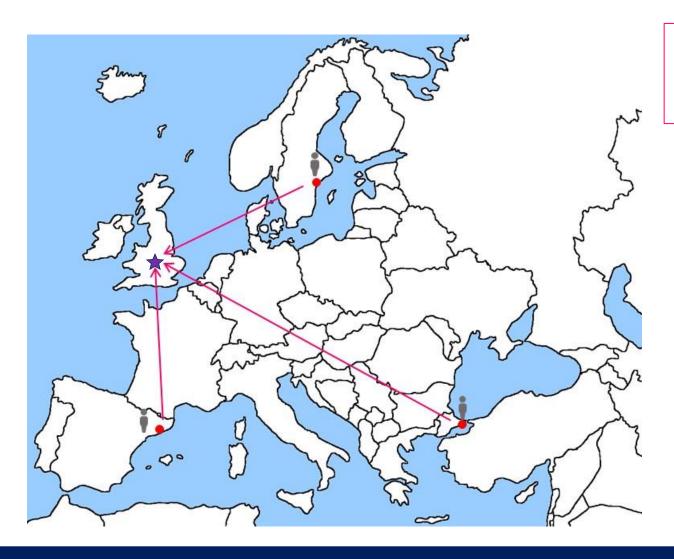
Watchful waiting

or

**Operative intervention** 



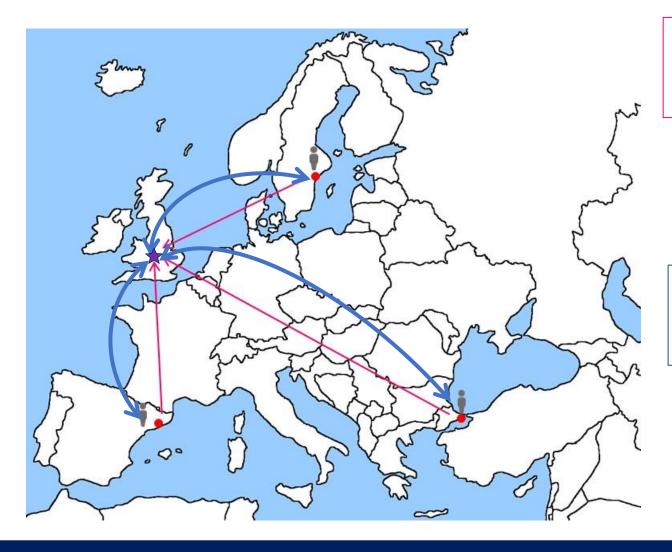
#### How



**SURGEON:** Operation technique and short-term (30 day) outcomes



#### How



**SURGEON: Operation technique** and short-term (30 day) outcomes



PATIENT: Long term outcomes, satisfaction, QOL up to 12 months

# Patient reported outcomes

• HR QOL

• Stoma Impact Score

Measure Yourself Medical Outcomes Profile (MYMOP)

Decision Regret















#### \* MYMOP2 \*

| Full name        |                      |                        |           | Dat               |            |            | Date of birth |                       |  |
|------------------|----------------------|------------------------|-----------|-------------------|------------|------------|---------------|-----------------------|--|
|                  | postcode             |                        |           |                   |            |            |               |                       |  |
|                  |                      |                        |           | Practitioner seen |            |            |               |                       |  |
| Choose one o     | or two symptoms      | physical or mer        | ntal) wh  | nich both         | er you th  | e most.    | Write the     | m on the lines.       |  |
| Now consider     | how bad each sy      | mptom is, over         | the las   | t week, a         | ind scon   | e it by ci | rcling you    | chosen number         |  |
| SYMPTOM 1        |                      | 0                      | 1         | 2                 | 3          | 4          | 5             | 6                     |  |
|                  |                      | As good as it could be |           |                   |            |            |               | As bad as it could be |  |
| SYMPTOM 2        | 1011011111111        | 0                      | 1         | 2                 | 3          | 4          | 5             | 6                     |  |
|                  |                      | As good as it could be |           |                   |            |            |               | As bad as it could be |  |
| Now choose of    | one activity (physi  | cal, social or m       | ental) ti | hat is imp        | portant to | o you, ar  | nd that you   | ır problem make       |  |
| difficult or pre | vents you doing.     | Score how bad          | it has    | been in t         | he last w  | reek.      |               |                       |  |
| ACTIVITY:        |                      | 0                      | 1         | 2                 | 3          | 4          | 5             | 6                     |  |
|                  |                      | As good as it could be |           |                   |            |            |               | As bad as it could be |  |
| Lastly how wo    | ould you rate your   | general feeling        | of well   | being du          | ring the   | last wee   | k?            |                       |  |
|                  |                      | 0                      | 1         | 2                 | 3          | 4          | 5             | 6                     |  |
|                  |                      | As good as it could be |           |                   |            |            |               | As bed as it could be |  |
| How long hav     | e you had Sympt      | om 1, either all       | the time  | e or on a         | nd off?    | Please     | circle:       |                       |  |
| 0 - 4 weeks      | 4 - 12 weeks         | 3 months - 1           | year      | 1 - 5             | years      | over       | 5 years       |                       |  |
| Are you takin    | g any medication     | FOR THIS PR            | OBLEN     | ? Plea            | se circle  |            | YES/A         | 10                    |  |
| IF YES:          |                      |                        |           |                   |            |            |               |                       |  |
| 1. Please writ   | e in name of med     | lication, and hor      | w much    | a day/w           | eek        |            |               |                       |  |
| 2. Is cutting d  | own this medicati    | on: Please circ        | le:       | ******            |            |            |               |                       |  |
| Not important    | a bit in             | nportant               | very      | importar          | nt         | not a      | pplicable     |                       |  |
| IF NO:           |                      |                        |           |                   |            |            |               |                       |  |
| Is avoiding m    | edication for this ; | problem:               |           |                   |            |            |               |                       |  |
| Not important    | a bit in             | nportant               | very      | importar          | nt .       | not a      | pplicable     |                       |  |

#### **Decision Regret Scale**

Please think about the decision you made about \_\_\_\_\_\_ after talking to your [doctor, surgeon, nurse, health professional, etc.]. Please show how you feel about these statements by circling a number from 1 (strongly agree) to 5 (strongly disagree).

| 1. | It was the right decision                                   | 1<br>Strongly<br>Agree | 2<br>Agree | 3<br>Neither<br>Agree Nor<br>Disagree | 4<br>Disagree | 5<br>Strongly<br>Disagree |
|----|---|------------------------|------------|---------------------------------------|---------------|---------------------------|
| 2. | I regret the choice that was made                           | 1<br>Strongly<br>Agree | 2<br>Agree | 3<br>Neither<br>Agree Nor<br>Disagree | 4<br>Disagree | 5<br>Strongly<br>Disagree |
| 3. | I would go for the same choice if I had to do it over again | 1<br>Strongly<br>Agree | 2<br>Agree | 3<br>Neither<br>Agree Nor<br>Disagree | 4<br>Disagree | 5<br>Strongly<br>Disagree |
| 4. | The choice did me a lot of harm                             | 1<br>Strongly<br>Agree | 2<br>Agree | 3<br>Neither<br>Agree Nor<br>Disagree | 4<br>Disagree | 5<br>Strongly<br>Disagree |
| 5. | The decision was a wise one                                 | 1<br>Strongly<br>Agree | 2<br>Agree | 3<br>Neither<br>Agree Nor<br>Disagree | 4<br>Disagree | 5<br>Strongly<br>Disagree |

Decision Regret Scale © AM O'Connor, 1996 University of Ottawa

# **Steering Group**

- Sue Blackwell
- Tom Pinkney
- Baljit Singh
- Imran Aslam
- Amanda Gunning
- Elizabeth Li
- Laura Magill
- Helle Ø Kristensen
- Katrine J Emmertsen
- Peter Christensen
- Tomas Poskus
- Neil Smart

**ACPGBI Patient Liaison Group** 

**Professor of Colorectal Surgery** 

**Consultant Colorectal Surgeon** 

Surgical Fellow

Senior Stoma Care Nurse

Clinical Research Fellow

Senior Lecturer in Clinical Trials

Research Fellow

Consultant Colorectal Surgeon

**Professor of Surgery** 

**Professor of Surgery** 

Consultant Colorectal Surgeon

Liverpool

Birmingham

Leicester

Leicester

Exeter

Birmingham

Birmingham CTU

Aarhus

Randers Hospital

Aarhus

Vilnius

Exeter

#### Get in contact



https://is.gd/propher\_signup



@PropherStudy

#### SUMMARY

- PSH are common, often symptomatic & reduce HRQOL. Consumes health care resources.
- Best method for stoma creation unknown ongoing research – CIPHER study.
- Repair is challenging best options being explored in PROPHER

