Bijlage 8 Evidencetabellen

Uitgangsvraag 3.3 Operatieve benadering

Uitgangsvraag:
Wat is het effect van operatie op morbiditeit, functie, kwaliteit van leven en overleving bij een ileus bij patiënten met kanker in de palliatieve fase?

Patiëntengroep: Patiënten met ileus en kanker
Intervention: Operatie
Comparison: Geen operatie
Outcome: Braken, mortaliteit. morbiditeit en kwaliteit van leven

Primary studies

I Study ID	II Method	III Patient characteristics	IV Intervention(s)	V Results	VII Critical appraisal of study quality	GRADE assessment
• **Fiori** et al. (2012) and **Fiori** et al. (2004)	• RCT • No conflicts of interest reported. • Setting: Department of Surgery "Pietro Valdoni" of the University of Rome "La Sapienza", Italy • Sample size: 22 • Follow-up: not reported. • No protocol existence reported.	• **Eligibility criteria:** Patients with malignant rectosigmoidal obstruction • **Patient characteristics:** • Age: stent: 77.2 (SD:3.3), colostomy: 76 (SD:4.6) • Sex: 13 men and 9 women.	• endoscopic stenting versus • colostomy	**Vomiting** • Not reported **Mortality** (defined as early mortality during hospital stay) • Intervention: 0/11 • Control: 0/11 **Morbidity** • Intervention: 0/11 • Control: 1/11 (colostomy prolapse 3 days after the operation). • P-value: Not significant **Quality of life:** • Not reported	• Unclear risk of bias due to no description of allocation concealment, blinding, incomplete outcome data, and selective outcome reporting.	• Low quality of evidence due to risk of bias and imprecision.

* self-calculated

Referenties
[1]Fiori E, Lamazza A, Cesare A, et al. Palliative management of malignant rectosigmoidal obstruction. Colostomy vs. endoscopic stenting. A randomized prospective trial. *Anticancer research* 2004:265-8.
[2]Fiori E, Lamazza A, Schillaci A, et al. Palliative management for patients with subacute obstruction and stage IV unresectable rectosigmoid cancer: Colostomy versus endoscopic stenting: Final results of a prospective randomized trial. American Journal of Surgery. 2012; 204: 321-26.

Uitgangsvraag 3.4 Stentplaatsing

Uitgangsvraag:
Wat is het effect van stentplaatsing op morbiditeit, functie, kwaliteit van leven en overleving bij een ileus bij patiënten met kanker in de palliatieve fase?

Patiëntengroep: Patiënten met ileus en kanker
Intervention: Stent
Comparison: Geen stent
Outcome: Braken, mortaliteit, morbiditeit en kwaliteit van leven

Primary studies

I Study ID	II Method	III Patient characteristics	IV Intervention(s)	V Results	VII Critical appraisal of study quality	GRADE assessment
• **Fiori** et al. (2012) and **Fiori** et al. (2004)	• RCT • No conflicts of interest reported. • Setting: Department of Surgery "Pietro Valdoni" of the University of Rome "La Sapienza", Italy • Sample size: 22 • Follow-up: not reported. • No protocol existence reported.	• **Eligibility criteria:** Patients with malignant rectosigmoidal obstruction • **Patient characteristics:** • Age: stent: 77.2 (SD:3.3), colostomy: 76 (SD:4.6) • Sex: 13 men and 9 women.	• endoscopic stenting (n=11) versus • Colostomy (n=11)	**Vomiting** • Not reported **Mortality** (defined as early mortality during hospital stay) • Intervention: 0/11 • Control: 0/11 **Morbidity** • Intervention: 0/11 • Control: 1/11 (colostomy prolapse 3 days after the operation). • P-value: Not significant **Quality of life:** • Not reported	• Unclear risk of bias due to no description of allocation concealment, blinding, incomplete outcome data, and selective outcome reporting.	• Low quality of evidence due to risk of bias and imprecision.
• **Young** et al. (2015)	• RCT • Conflicts of interest reported and none known. • Setting: Royal Prince Alfred Hospital, Sydney, and Western Hospital, Melbourne. • Sample size: 56 • Follow-up: 12 months.	• **Eligibility criteria:** All patients ≥18 years who presented between September 2006 and November 2011 with a malignant LBO, deemed not curable by surgical intervention (assessed in a multidisciplinary team meeting where possible because of the	• stent insertion group (n=26) versus • surgical decompression group (n=26)	**Vomiting** • Not reported **Mortality** (defined as median survival) • Intervention: 5.2 months (SE:3.1, 95%-CI: 0.0-11.5) • Control: 5.5 months (SE:0.6, 95%-CI: 4.2-6.7) • P-value: 0.61 **Morbidity** (defined as early postprocedure complications)	• High risk of bias due to no blinding of surgeons and patients.	• Low quality of evidence due to risk of bias and imprecision.

	• Protocol: ACTRN012606000199516	emergency nature of cases). • **Patient characteristics:** • Age: stent: 66 (SD:11), surgery: 67 (SD:14) • Sex (% male): stent: 65%, surgery: 69%		• Intervention: 10/26 • Control: 14/26 • P-value: 0.40 **Morbidity** (defined as at least one complication over the first 12 months after the procedure) • Intervention: 15/26 • Control: 18/26 • P-value: 0.56 **Quality of life:** • no significant difference in EQ-5D scores at any time point between treatment groups.		

Systematic reviews

I Study ID	II Method	III Patient characteristics	IV Intervention(s)	V Results	VII Critical appraisal of study quality	GRADE assessment
• **Cirocchi** et al. (2013)	• Design: systematic review with meta-analysis. • Conflicts of interest reported and none known. • Search date: December 2011 • Searched databases: Medline, Central, and Science Citation Index • Included study designs: only RCTs. • Number of included studies: 3 studies. • No protocol reported.	• Eligibility criteria: Adult patients with large bowel obstruction secondary to left colon and rectal cancer were enrolled irrespective of gender and comorbidities.	• Emergency surgery versus • colonic stenting and subsequently elective surgical resection	**Vomiting** • Not reported **Mortality** (defined as thirty days postoperative mortality) • Control: 9% • Intervention: 8.2% • OR: 0.99 (95%-CI: 0.23-4.19) **Morbidity** (defined as overall complication rate) • Control: 48.45% • Intervention: 51% • OR: 0.90 (95%-CI:0.52-1.58) **Quality of life:** • Not reported	• Unclear risk of bias due to no description of a protocol and assessment of publication bias.	• Low quality of evidence due to risk of bias and imprecision.

Referenties

[1]Fiori E, Lamazza A, Cesare A, et al. Palliative management of malignant rectosigmoidal obstruction. Colostomy vs. endoscopic stenting. A randomized prospective trial. 2004:265-8.

[2]Young CJ, De-Loyde KJ, Young JM, et al. Improving Quality of Life for People with Incurable Large-Bowel Obstruction: Randomized Control Trial of Colonic Stent Insertion. Diseases of the colon and rectum. 2015; 58: 838-49.

[3]Cirocchi R, Farinella E, Trastulli S, et al. Safety and efficacy of endoscopic colonic stenting as a bridge to surgery in the management of intestinal obstruction due to left colon and rectal cancer: a systematic review and meta-analysis. Surgical oncology. 2013; 22: 14-21. 10.1016/j.suronc.2012.10.003.

{Cirocchi, 2013 #41;Fiori, 2004 #177;Young, 2015 #233}{Cirocchi, 2013 #41;Fiori, 2004 #177;Young, 2015 #233}

Uitgangsvraag 3.5 Maaghevel

Wat is het effect van een maaghevel op braken en kwaliteit van leven bij een ileus bij patiënten met kanker in de palliatieve fase?

Patiëntengroep: Patiënten met ileus en kanker
Intervention: Een maaghevel
Comparison: Geen maaghevel
Outcome: Braken en kwaliteit van leven.

Beschrijving van de studies

Er is geen enkele gerandomiseerde vergelijkende studie gevonden die het effect evalueerde van een maaghevel op het braken en kwaliteit van leven bij patiënten met ileus en kanker.

Conclusies

Er kan op basis van het systematische literatuuronderzoek geen uitspraak worden gedaan over de invloed van een maaghevel op braken en kwaliteit van leven bij patiënten met ileus en kanker in de palliatieve fase.

Uitgangsvraag 3.6.2 Octreotide/lanreotide

Uitgangsvraag:
Wat is het effect van octreotide / lanreotide op braken, maaghevelproductie en kwaliteit van leven bij een ileus bij patiënten met kanker in de palliatieve fase?

Patiëntengroep: Patiënten met ileus en kanker
Intervention: Octreotide / Lanreotide
Comparison: Geen octreotide / lanreotide
Outcome: Braken, kwaliteit van leven en GI-secretions

Primary studies

I Study ID	II Method	III Patient characteristics	IV Intervention(s)	V Results	VII Critical appraisal of study quality	GRADE assessment
• **Currow** et al. (2015)	• RCT • Conflicts of interest reported and none known. • Setting: 12 palliative care service networks across Australia. • Sample size: 112 • Follow-up: not reported. • No protocol existence reported.	• **Eligibility criteria:** People with vomiting secondary to a malignant bowel obstruction where surgery or further anticancer therapies were not immediately appropriate were eligible • **Patient characteristics:** • Age: octreotide: 62.9 (SD:13.6), placebo: 66.3 (SD:12.2) • Sex (% female): octreotide: 90.4, placebo: 70.4	• Subcutaneous infusion of octreotide (600 mg/24 hours) (n=52) versus • Placebo (n=54)	**Free of vomiting at day three:** • Intervention: 17/52 • Control: 14/54 • P-value: 0.67 **Days free of vomiting:** • Intervention: 1.87 (SD: 1.10) • Control: 1.69 (SD: 1.15) • P-value: 0.47 **Quality of life:** • Not reported **GI-secretions:** • Not reported	• Unclear risk of bias due to no description of selective outcome reporting.	• Low quality of evidence due to risk of bias and imprecision.
• **Laval** et al. (2012)	• RCT • Two conflicts of interest are reported. • No details regarding the setting reported. • Sample size: 64 • Follow-up: 3 months • No protocol existence reported.	• **Eligibility criteria:** Patients aged above or equal to 18 years with inoperable symptomatic bowel obstruction. • **Patient characteristics:** • Age: 64.2 (SD: 11.0) • Sex: 28**%** male and 72% female.	• Octreotide 600 mg/day (n=32) versus • Placebo (n=32)	**<2 episodes of vomiting per day between days 10 and 13:** • Intervention: 19/21 • Control: 13/15 • P-value: Not significant. **Quality of life:** • Not reported **GI-secretions:** • Not reported	• High risk of bias due to high number of missing patients in the outcomes of interest.	• Low quality of evidence due to risk of bias and imprecision.

• **Mariani** et al. (2012)	• RCT • Several conflicts of interest reported. • Setting: 22 hospitals across Belgium, France, and the Netherlands. • Sample size: 80 • Follow-up: 10-days • Protocol: NCT00216372.	• **Eligibility criteria:** Adults (older than 18 years of age) with peritoneal carcinomatosis (confirmed by computed tomography within the previous 3 months) were eligible if they had a digestive obstruction (stomach, duodenum, or small bowel) of malignant origin and were experiencing two or more vomiting episodes per day or had an NGT, and if surgery was inappropriate • **Patient characteristics:** • Age: intervention: 62.5 (SD:10.0), control: 62.2 (SD:13.2) • Sex (% female): intervention: 81.4, placebo: 83.8	• Lanreotide microparticles, 30 mg (n=43) versus • Placebo (n=37)	**Time without vomiting over days 1-7 (days, SD)** • Intervention: 5.0 (SD: 2.0) • Control: 4.6 (SD: 2.6) • P-value: 0.77 **Quality of life:** • Not reported **GI-secretions:** • Not reported	• Low risk of bias.	• Moderate quality of evidence due to imprecision.
• **Mercadente** et al. (2000)	• RCT • No conflicts of interest reported. • Two different settings: home care and surgical or oncological ward, • Sample size: 18 • Follow-up: 3 days • No protocol existence reported.	• **Eligibility criteria:** Patients with inoperable bowel obstruction. • **Patient characteristics:** • No average age reported. • No details about gender reported.	• Octreotide 0.3 mg daily (n=9) versus • 60 mg of hyoscine butylbromide (n=9)	**Vomiting episodes at day three** • Intervention: 1.0 (SD: 0.6) • Control: 2.4 (SD: 0.7) • P-value: not significant **Quality of life:** • Not reported **GI-secretions:** • Not reported	• Unclear risk of bias due to no description of randomisation, allocation concealment, blinding, selective outcome reporting, and incomplete outcome data.	• Low quality of evidence due to risk of bias and imprecision.
• **Mystakidou** et al (2002)	• RCT • No conflicts of interest reported. • Setting: Palliative Care Unit of the Areteion Hospital, Athens, Greece. • Sample size: 68 • Follow-up: until death of patients. • No protocol existence reported. •	• **Eligibility criteria:** Advanced cancer with metastasis which was no longer responsive to antitumor treatment. The patients were under analgesic medication according to the WHO analgesic ladder. • **Patients characteristics:**	• Chlorpromazine (15-25 mg/day) in addition to hyoscine butylbromide (60-80 mg/day) (n=34) versus • Chlorpomazine (15-25 mg/day) with octreotide	**Number of vomiting episodes per day measured on the day before death** • Intervention: 0.59 (SD:0.50) • Control: 0.55 (SD: 0.51) • MD: 0.04 (95%-CI: -0.24-0.32)* **GI-secretions:** • Not reported	• High risk of bias due to the a high number of patients lost to follow-up.	• Low quality of evidence due to risk of bias and imprecision.

		• Age (median – range): intervention: 63 (47-74), control: 64.5 (42.77). • Gender: intervention: 18 female, 16 male. Control: 14 female, 20 male.	(0.6-0.8mg/day). (n=22) •			
• **Peng** et al. (2015)	• RCT • Conflict of interest reported and none known. • Setting: general surgery, Qilu Hospital of Shandong University • Sample size: 97 • Follow-up: 3 days • No protocol existence reported.	• **Eligibility criteria:** Diagnosis of documented recurrence of ovarian cancer and the presence of a bowel obstruction based on a compilation of clinical signs, symptoms, and/or radiographic evidence • **Patient characteristics:** • Age: Intervention: 54.2 (SD: 7.3), control: 53.2 (SD:7.9) • All females	• Octreotide 0.3 mg daily (n=48) versus • 60 mg of scopolamine butylbromide (n=49)	**Vomiting episodes at day three** • Intervention: 1.2 (SD: 0.5) • Control: 2.0 (SD: 0.8) • P-value: not significant **Quality of life:** • Not reported **GI-secretions:** • Not reported	• Unclear risk of bias due to no description of allocation concealment, blinding, selective outcome reporting, and incomplete outcome data.	• Low quality of evidence due to risk of bias and imprecision.
• **Ripamonti** et al. (2000).	• RCT • No conflicts of interest reported. • Setting: Oncological Surgery Divisions of the National Cancer Institute of Milan. • Sample size: 17 • Follow-up: 3 days • No protocol existence reported.	• **Eligibility criteria:** All the patients presented with a decompressive nasogastric tube and a clinical and/or radiological and/or surgical diagnosis of inoperative bowel obstruction in whom available oncologic therapies for tumor control had been exhausted. • **Patients characteristics:** • Mean age (SD): 61.12 (9.0) • Gender: 11 female / 6 male.	• Octreotide 0.3 mg daily (n=9) Versus • Scopolamine butylbromide (n=8)	**Vomiting episodes at day three** • Not reported **Quality of life:** • Not reported **GI-secretions:** • No quantitative values of GI secretion reported excepted for a statistically significant lower GI-secretions between the Oceotride and scopolamine butylbromide group (p=0.016 & p=0.020)	• Unclear risk of bias due to no description of randomisation, allocation concealment, blinding, selective outcome reporting, and incomplete outcome data.	• Very low quality of evidence due to risk of bias and imprecision (twice).

Referenties

[1-7]

[1] Currow DC, Quinn S, Agar M, et al. Double-blind, placebo-controlled, randomized trial of octreotide in malignant bowel obstruction. 2015:814-21.10.1016/j.jpainsymman.2014.09.013.

[2] Laval G, Rousselot H, Toussaint-Martel S, et al. SALTO: a randomized, multicenter study assessing octreotide LAR in inoperable bowel obstruction. Bull Cancer. 2012; 99: E1-9. 10.1684/bdc.2011.1535.

[3] Mariani P, Blumberg J, Landau A, et al. Symptomatic treatment with lanreotide microparticles in inoperable bowel obstruction resulting from peritoneal carcinomatosis: a randomized, double-blind, placebo-controlled phase III study. 2012:4337-43.10.1200/JCO.2011.40.5712.
[4] Mercadante S, Ripamonti C, Casuccio A, et al. Comparison of octreotide and hyoscine butylbromide in controlling gastrointestinal symptoms due to malignant inoperable bowel obstruction. 2000:188-91.
[5] Peng X, Wang P, Li S, et al. Randomized clinical trial comparing octreotide and scopolamine butylbromide in symptom control of patients with inoperable bowel obstruction due to advanced ovarian cancer. 2015.10.1186/s12957-015-0455-3.
[6] Mystakidou K, Tsilika E, Kalaidopoulou O, et al. Comparison of octreotide administration vs conservative treatment in the management of inoperable bowel obstruction in patients with far advanced cancer: a randomized, double- blind, controlled clinical trial. *Anticancer research* 2002:1187-92.
[7] Ripamonti C, Mercadante S, Groff L, et al. Role of octreotide, scopolamine butylbromide, and hydration in symptom control of patients with inoperable bowel obstruction and nasogastric tubes: a prospective randomized trial. 2000:23-34.

Uitgangsvraag 3.6.4 Scopolaminebutyl

Uitgangsvraag:
Wat is het effect van scopolaminebutyl op braken, maaghevelproductie en kwaliteit van leven bij een ileus bij patiënten met kanker in de palliatieve fase?

Patiëntengroep: Patiënten met ileus en kanker
Intervention: Butylscopolamine
Comparison: Geen butylscopolamine
Outcome: Braken en kwaliteit van leven.

Primary studies

I Study ID	II Method	III Patient characteristics	IV Intervention(s)	V Results	VII Critical appraisal of study quality	GRADE assessment
• **Mercadente** et al. (2000)	• RCT • No conflicts of interest reported. • Two different settings: home care and surgical or oncological ward, • Sample size: 18 • Follow-up: 3 days • No protocol existence reported.	• **Eligibility criteria:** Patients with inoperable bowel obstruction. • **Patient characteristics:** • No average age reported. • No details about gender reported.	• 60 mg of hyoscine butylbromide (n=9) Versus • Octreotide 0.3 mg daily (n=9)	**Vomiting episodes at day three** • Intervention: 2.4 (SD: 0.7) • Control: 1.0 (SD: 0.6) • P-value: not significant **Quality of life:** Not reported	• Unclear risk of bias due to no description of randomisation, allocation concealment, blinding, selective outcome reporting, and incomplete outcome data.	• Low quality of evidence due to risk of bias and imprecision.
• **Mystakidou** et al (2002)	• RCT • No conflicts of interest reported. • Setting: Palliative Care Unit of the Areteion Hospital, Athens, Greece. • Sample size: 68 • Follow-up: until death of patients. • No protocol existence reported.	• **Eligibility criteria:** Advanced cancer with metastasis which was no longer responsive to antitumor treatment. The patients were under analgesic medication according to the WHO analgesic ladder. • **Patients characteristics:** • Age (median – range): intervention: 63 (47-74), control: 64.5 (42.77).	• Chlorpromazine (15-25 mg/day) in addition to hyoscine butylbromide (60-80 mg/day) (n=34) versus • Chlorpomazine (15-25 mg/day) with octreotide (0.6-0.8mg/day). (n=22)	**Number of vomiting episodes per day measured on the day before death** • Intervention: 0.59 (SD:0.50) • Control: 0.55 (SD: 0.51) • MD: 0.04 (95%-CI: -0.24-0.32)*	• High risk of bias due to the a high number of patients lost to follow-up.	• Low quality of evidence due to risk of bias and imprecision.

		• Gender: intervention: 18 female, 16 male. Control: 14 female, 20 male.				
• **Peng** et al. (2015)	• RCT • Conflict of interest reported and none known. • Setting: general surgery, Qilu Hospital of Shandong University • Sample size: 97 • Follow-up: 3 days • No protocol existence reported.	• **Eligibility criteria:** Diagnosis of documented recurrence of ovarian cancer and the presence of a bowel obstruction based on a compilation of clinical signs, symptoms, and/or radiographic evidence • **Patient characteristics:** • Age: Intervention: 54.2 (SD: 7.3), control: 53.2 (SD:7.9) • All females	• 60 mg of scopolamine butylbromide (n=49) versus • Octreotide 0.3 mg daily (n=48)	**Vomiting episodes at day three** • Intervention: 2.0 (SD: 0.8) • Control : 1.2 (SD: 0.5) • P-value: not significant **Quality of life:** Not reported	• Unclear risk of bias due to no description of allocation concealment, blinding, selective outcome reporting, and incomplete outcome data.	• Low quality of evidence due to risk of bias and imprecision.
• **Ripamonti** et al. (2000).	• RCT • No conflicts of interest reported. • Setting: Oncological Surgery Divisions of the National Cancer Institute of Milan. • Sample size: 17 • Follow-up: 3 days • No protocol existence reported.	• **Eligibility criteria:** All the patients presented with a decompressive nasogastric tube and a clinical and/or radiological and/or surgical diagnosis of inoperative bowel obstruction in whom available oncologic therapies for tumor control had been exhausted. • **Patients characteristics:** • Mean age (SD): 61.12 (9.0) • Gender: 11 female / 6 male.	• Octreotide 0.3 mg daily (n=9) Versus • Scopolamine butylbromide (n=8)	**Vomiting episodes at day three** • Not reported **Quality of life:** • Not reported **GI-secretions:** • No quantitative values of GI secretion reported excepted for a statistically significant lower GI-secretions between the Oceotride and scopolamine butylbromide group (p=0.016 & p=0.020)	• Unclear risk of bias due to no description of randomisation, allocation concealment, blinding, selective outcome reporting, and incomplete outcome data.	• Very low quality of evidence due to risk of bias and imprecision (twice).

* self-calculated

Referenties

[1-4]

[1] Mercadante S, Ripamonti C, Casuccio A, et al. Comparison of octreotide and hyoscine butylbromide in controlling gastrointestinal symptoms due to malignant inoperable bowel obstruction. 2000:188-91.

[2] Mystakidou K, Tsilika E, Kalaidopoulou O, et al. Comparison of octreotide administration vs conservative treatment in the management of inoperable bowel obstruction in patients with far advanced cancer: A randomized, double-blind, controlled clinical trial. Anticancer Research. 2002; 22: 1187-92.

[3] Peng X, Wang P, Li S, et al. Randomized clinical trial comparing octreotide and scopolamine butylbromide in symptom control of patients with inoperable bowel obstruction due to advanced ovarian cancer. 2015.10.1186/s12957-015-0455-3.

[4] Ripamonti C, Mercadante S, Groff L, et al. Role of octreotide, scopolamine butylbromide, and hydration in symptom control of patients with inoperable bowel obstruction and nasogastric tubes: a prospective randomized trial. 2000:23-34.