Abdominal Wall Hernia Cliff

Branch Baseline

Defects or weak points in the abdominal wall lead to the development of abdominal hernias. Hernias are relatively common, as groin (inguinal and femoral) hernia prevalence is estimated to be 5-10% in the United States. The white male population is at the highest risk for both development of a hernia and need for repair. The most common hernia types are inguinal, umbilical, incisional, and femoral. However, umbilical hernias are most common in the very young and the elderly or in the obese population (Dabbas, 2011). As current astronauts are medically qualified and, therefore, outside of these affected populations, this discussion will focus on the more likely etiologies of inguinal, incisional, and femoral hernias. The clinical spectrum of presentations and complications related to abdominal hernias is variable, ranging from uncomplicated identification of an asymptomatic hernia to incarceration and strangulation of bowel resulting in intestinal ischemia and even perforation (Fitzgibbons, Jr., 2006). Symptoms can range from the patient noticing a bulge in the groin region or at an old incisional site, with or without pain, to a severe and emergent presentation of acute bowel strangulation, with severe pain, signs of bowel obstruction, and even signs and symptoms of acute shock. Differentiating between hernia types is relatively straight forward in a non-obese patient, as femoral hernias present inferior to the inguinal ligament and medial to the femoral artery and inguinal hernias often present with a bulge near the inguinal canal or, in males, with invagination of bowel into the scrotum. Incisional hernias present at the site of a prior surgery. The differential diagnosis includes any pathology producing pain or a mass in the groin, including testicular torsion, epididymitis, hydrocele, varicocele, spermatocele, epididymal cyst, and testicular tumor. Diagnosis can be made with ultrasound imaging, with indirect inguinal hernias identified with a 97% sensitivity and 87% specificity, and identification of femoral hernias with reported rates of 100% sensitivity and specificity (Bradley, 2003). Hernias are more common in males and can occur at any age, though femoral hernias are more common in women particularly over the age of 60 (Dabbas, 2011)(Naude, 1997). Elective surgical repair of hernias has become quite common, with surgical procedures ranging from open laparotomy and suture or mesh repair to laparoscopic and minimally invasive surgery (Anon., 2000). Post-repair recurrence is common (Kingsnorth, 2003). Incisional hernias occur after prior abdominal surgery; abdominal incisions are associated with a 10-15% risk of incisional hernia, with increased risk associated with smoking, obesity, and postoperative infection (George, 1986). The ICD-10 codes abdominal hernias by anatomical site (inguinal, femoral, incisional, and umbilical), recurrence, and complication (gangrene, incarceration, irreducible, obstruction, and perforation).

Incidence Data Included in the Model

The model imports the following incidence information from the IMM database: incidence data category, space adaption status, incidence data, incidence and occurrence distribution data and incidence data characteristics. Data category defines the type of data available for incidence calculations (i.e. raw data vs. fixed data). Space adaptation identifies medical events that onset occurs in the first 5 days of flight and does not reoccur. Incidence values vary by data category and define the number of medical events per person-year or medical events per person-at-risk for each medical condition. Incidence values can be modified by crew characteristics such as gender. Modifying characteristics are noted below and incidence values are listed individually for each characteristic. Distributions are assigned to medical events incidence values and occurrences in the model. For each crew member in a given trial, the incidence and number of occurrences of each medical condition are randomly selected from these probability distributions. Detailed descriptions of the distributions are included in the IMM Technical Description Document.

Incidence	
Data Category:	Raw Data
Space Adaptation:	No
Incidence Type:	Rate

Distribution Data	
Incidence:	Gamma
Occurrence:	Poisson

Data Characteristics	
Events:	89000
Person Years:	197515528
Space Flight Incidence Rate (Events / Person Years):	89000 / 197515528 = 0.000450597484163372

Incidence Comments

No cases of abdominal wall hernias have occurred in-flight (Walton, 2010).

General population data regarding the incidence rate of abdominal wall hernias was obtained from a longitudinal, nationally representative, population-based study that was conducted on the incidence of abdominal wall hernias among the general U.S. population using data from the National Ambulatory Medical Care Survey (NAMCS) and National Hospital Ambulatory Medical Care Survey (NHAMCS), 3-year average 2003 to 2005 (Everhart, 2008). Gender and race data in this source do not differentiate by age, thus incidence rates differentiating between males and females, and whites and blacks, have not been included in this calculation. Only data for the hospital discharges, first-listed diagnoses were included, as this data is presumably more reliable than data from ambulatory care visits. Age ranges for which data was provided were 15-44 and 45-64.

Hospital Discharges, First-Listed Diagnosis, Age 15-44, approximately 29,000 events at a rate of 23 per 100,000 (0.00023 per person-year). Total person-years were calculated at 126,086,957 (dividing 29,000 by 0.00023).

Hospital Discharges, First-Listed Diagnosis, Age 45-64, approximately 60,000 events at a rate of 84 per 100,000 (0.00084 per person-year). Total person-years were calculated at 71,428,571 (dividing 60,000 by 0.00084).

Cumulative incidence for both age groups was calculated at 0.00045 events/person-year:

(29,000+60,000) events divided by (126,086,957 + 71428571) person-years (Everhart, 2008).

Information Regarding Prevention

ISS 50667 Medical Evaluation Documents comprise three volumes. (Volume A, B, and C)

Volume B contains the elements of examination of ISS crewmembers assigned to long-duration space flights. This document (MED Volume B) details the medical evaluation requirements for preflight, inflight,and postflight phases of ISS missions. The medical evaluations are designated for all Volume C includes the medical standards for Space Flight Participants (International Space Station Program, 2011).

Incidence Level of Evidence (LOE)

The IMM level of evidence appropriate assessment of the quality of the IMM input data. Since IMM incorporates input data from a wide variety of sources including astronaut population, terrestrial or analog populations, and external models, an innovative approach to assess the quality of input data was required. Information obtained from the astronaut population and/or space flight is the more relevant so it is assigned the highest level of evidence and less relevant data sources are assigned a lower level of evidence.

Citation	LOE Value	LOE Category
Everhart, 2008	4	Incidence

Treatment and Outcomes

Based on the best evidence available best and worst case percentage ranges are assigned. The medical condition is divided into three clinical phases in all three clinical phases a functional impairment is assigned. The clinical phase I and II's functional impairments remain for the duration for that respective clinical phase. The function impairment in clinical phase III represents final impairment for this medical condition and remains for the rest of the mission. Other mission end states include evacuation and loss of crew life.

The IMM checks medical resource availability once the number of medical events and scenarios has been established. If there is not sufficient essential resources called out in the CliFF, then the medical condition will go down an untreated best or worst case scenario pathway.

The table below summarizes the treated and untreated best and worst case scenarios.

	Clinical Phase I Diagnosis & Initial Treatment[1]		**Clinical Phase II On-going Treatment / Convalescence[2]**		**Clinical Phase III Recovered / Mission End State[3]**		
	FI[*] (%)	**Duration (hrs)**	**FI[*] (%)**	**Duration (hrs) (Min - ML - Max)**	**FI[*] (%)**	**EVAC[**] (%)**	**LOCL[**] (%)**
ISS-based Treatment (best case scenario %: 77 - 99)	100	2	2 - 22	24 - 24 - 24	0 - 10	0	0
ISS-based Treatment (worst case scenario %: 1 - 23)	100	2	13 - 37	24 - 24 - 24	0 - 37	100	0 - 5
Untreated Best Case	N/A	N/A	13 - 37	24 - 24 - 24	13 - 37	0 - 100	0
Untreated Worst Case	N/A	N/A	25 - 58	24 - 24 - 24	25 - 58	100	0 - 100

[1]Clinical Phase I: Clinical phase I covers only the initial assessment of the affected crew member to define his or her medical condition, and completion of appropriate initial treatment to stabilize the crew member. While the affected crew member is being assessed, he or she is not able to perform any assigned tasks, thus Functional Impairment during this phase is considered 100%. In the untreated case, there is no diagnosis performed or treatment given, therefore Functional Impairment and Duration will always be "not applicable".

[2]Clinical Phase II: On-going Treatment and Convalescence- During clinical phase II, the affected crew member is receiving any appropriate follow-on treatment for his or her medical condition to allow the crew member to recover as much as he or she is able to recover in the ISS environment. Clinical phase II also encompasses relapses or reoccurrences of the same original medical condition in clinical phase I necessitating additional treatment or recovery time due to unsuccessful primary treatment response. The duration in Clinical Phase II is expressed in minimum, most likely (ML) and maximum hours. This was updated for future capabilities in IMM but is currently not being used by the model.

[3]Clinical Phase III: Recovered/Mission End State- Clinical phase III is reached once the affected crew member has recovered from the medical condition as much as he or she is able to recover in the ISS environment. This may or may not be recovery from the given medical condition to the full extent possible. If this "recovered" state results in an evacuation or loss of the crew member, this will be noted in the mission end state results.

*Functional Impairment (FI) is a measure of the affected crew member's health and performance ability.

**Two mission end state results are addressed in the CliFF: 1) Evacuation (EVAC) - crew and patient are evacuated from the spacecraft due to the medical condition, and 2) Loss of crew (LOCL) - death of affected crew member due to medical condition. EVAC is considered as an end state result if any of the following criteria are met: 1) potential LOCL, 2) potential significant permanent impairment, or 3) potential intractable pain. Probability distributions are assigned for each range of values within the Table of Treatments and Outcomes.

Refer to the Integrated Medical Model Technical Document for more information on how risk is reported by the IMM, Crew Health Index (CHI) and Quality Adjusted Mission Time calculations.

Definition and Probability of Best and Worst Case Scenario: (includes definitions of best and worst case scenarios and identifies the probability of those scenarios.)

Scenario Comments

Inguinal hernias are the most common form of abdominal wall hernia (Ruhl, 2007). As such, percentages of how often best versus worst case scenarios occur were obtained from terrestrial data. This was a randomized trial from 1999-2004 that assigned 366 men with inguinal hernias into a watchful waiting group. Two were ineligible and excluded from the study making 364 the new denominator. Of this group, 85 eventually underwent repair with pain and discomfort as the driving reasons. Three cases, however, were at their own request so they were subtracted making 82 the new numerator. Based on the worst case definition of "Hernia requiring either emergent surgery due to complications, or non-emergent surgery due to severity of symptoms," the worst case treated upper limit was calculated as 0.23, or 23% [(82/364) x 100].

The study noted that one patient of the 364 experienced acute hernia incarceration without strangulation within two years, and another had acute incarceration with bowel obstruction at four years. Based on the same case definition, the worst case treated lower limit was calculated as 0.01, or 1% [(2/364) x 100].

The study included patients of the male gender only, and this is seen as a limitation since the astronaut core is mixed gender (Fitzgibbons, Jr., 2006).

Best Case Definition

Asymptomatic or mildy symptomatic hernia not requiring surgery.

Worst Case Definition

Hernia requiring either emergent surgery due to complications, or non-emergent surgery due to severity of symptoms.

The more common complications of abdominal wall hernias include bowel obstruction, incarceration, and strangulation. Bowel obstruction is addressed in the Small Bowel Obstruction CliFF.

Best Case Comments

Functional Impairment (FI) was derived by using the IMM severe non-space adaptation template. For Clinical Phase 3 only, we deviated from the template to account for more severe impairment. While pain management may provide symptomatic relief for an abdominal wall hernia, there is no treatment manifested that will reverse the condition. In other words, the underlying pathophysiology will remain unchanged and may potentially progress. As such, the Treated Best Case scenario, Clinical Phase 3, is represented by FI Class 0-1 and not Class 0.

Herniation disease ratings are based on Table 6-10, pg. 122 (American Medical Association, 2008). Complex Regional Pain Syndrome – Lower Extremity (CRPS-LEI) ratings are based on Table 16-15, pg. 541 (American Medical Association, 2008). The CRPS (LEI) ratings are then converted to a percentage of Whole Person Impairment (WPI), which are based on Table 16-1, pg. 495 (American Medical Association). Final ratings are calculated combining the Herniation FI and Whole Person Impairment using the Combined Values Chart as indicated in Appendix A, pgs. 604-606.

By definition, in Clinical Phase 1, FI is 100%. Duration to follow procedures, i.e. physical exam, vital signs, and abdominal ultrasound, is estimated at two hours. During Clinical Phase 2, FI is estimated between 2-22%. The duration is noted at 24 hours under the premise that once analgesics take effect, or a hernia is reduced, then pain will improve. In Clinical Phase 3, the FI is between 0-10% for the reasons mentioned earlier. By definition EVAL and LOCL would not be expected for the best case scenario.

Worst Case Comments

Functional Impairment (FI) was derived by using the IMM severe non-space adaptation template. Herniation disease ratings are based on Table 6-10, pg. 122 (American Medical Association, 2008). Complex Regional Pain Syndrome – Lower Extremity (CRPS-LEI) ratings are based on Table 16-15, pg. 541 (American Medical Association, 2008). The CRPS (LEI) ratings are then converted to a percentage of Whole Person Impairment (WPI), which are based on Table 16-1, pg. 495. Final ratings are calculated combining the Herniation FI and Whole Person Impairment using the Combined Values Chart as indicated in Appendix A, pgs. 604-606.

By definition, in Clinical Phase 1, FI is 100%. Duration to follow procedures, i.e. physical exam, vital signs, and abdominal ultrasound, is estimated at two hours. During Clinical Phase 2, FI is estimated between 13-37%. The duration is noted at 24 hours under the premise that all treated worst case scenarios will proceed to EVAC. In Clinical Phase 3, the FI is between 0-37%. LOCL is estimated as 0-5%. This is based upon a terrestrial, retrospective multicenter study of all patients who underwent emergency surgical repair of an abdominal wall hernia (Martinez-Serrano, 2010). Of the 402 patients in the study, 18 patients died (4.5%). A conservative approach accounting for younger age provides a LOCL range from 0-5%.

Untreated Best Case Comments

Functional Impairment (FI) was derived by using the IMM severe non-space adaptation template. For Clinical Phase 3 only, we deviated from the template to account for more severe impairment. While pain management may provide symptomatic relief for an abdominal wall hernia, there is no treatment manifested that will reverse the condition. In other words, the underlying pathophysiology will remain unchanged and may potentially progress. As such, the Untreated Best Case scenario, Clinical Phase 3 is represented by FI Class 2-3 and not Class 0-2.

Herniation disease ratings are based on Table 6-10, pg. 122 (American Medical Association, 2008). Complex Regional Pain Syndrome – Lower Extremity (CRPS-LEI) ratings are based on Table 16-15, pg. 541 (American Medical Association, 2008). The CRPS (LEI) ratings are then converted to a percentage of Whole Person Impairment (WPI), which are based on Table 16-1, pg. 495. Final ratings are calculated combining the Herniation FI and Whole Person Impairment using the Combined Values Chart as indicated in Appendix A, pgs. 604-606 During Clinical Phase 2, FI is estimated between 13-37%. The duration is noted at 24 hours under the premise that once analgesics take effect, or a hernia is reduced, then pain will improve. In Clinical Phase 3, the FI is between 13-37% for the reasons mentioned earlier. EVAC is estimated between 0-100% to account for uncertainty of potential long term complications. LOCL would not be expected for this scenario.

Untreated Worst Case Comments

Functional Impairment (FI) was derived by using the IMM severe non-space adaptation template. Herniation disease ratings are based on Table 6-10, pg. 122 (American Medical Association, 2008). Complex Regional Pain Syndrome – Lower Extremity (CRPS-LEI) ratings are based on Table 16-15, pg. 541. The CRPS (LEI) ratings are then converted to a percentage of Whole Person Impairment (WPI), which are based on Table 16-1, pg. 495 (American Medical Association, 2008). Final ratings are calculated combining the Herniation FI and Whole Person Impairment using the Combined Values Chart as indicated in Appendix A, pgs. 604-606.

During Clinical Phase 2, FI is estimated between 25-58%. The duration is noted at 24 hours under the premise that all untreated worst case scenarios will proceed to EVAC . In Clinical Phase 3, the FI is between 25-58%. LOCL is estimated as 0-100% to account for uncertainty in clinical severity.

Treatment and Options Level of Evidence (LOE)

The IMM level of evidence appropriate assessment of the quality of the IMM input data. Since IMM incorporates input data from a wide variety of sources including astronaut population, terrestrial or analog populations, and external models, an innovative approach to assess the quality of input data was required. Information obtained from the astronaut population and/or space flight is the more relevant so it is assigned the highest level of evidence and less relevant data sources are assigned a lower level of evidence.

Citation	LOE Value	LOE Category
Ruhl, 2007	4	BCWC
Fitzgibbons, Jr., 2006	4	BCWC
American Medical Association, 2008	3	FI
American Medical Association, 2008	3	FI
Martinez-Serrano, 2010	4	EVAC

Additional Comments

Key word used in library searchs: abdominal, hernia, herniation, inguinal, direct, femoral, mortality, ultrasound, imagining, diagnositics.

The Resource Table (RT)

Resource	Units Required Best Case	Units Required Worst Case	Units Available At Start Of Mission	Consumable	Essential	Rationale
BZK wipes	0	2	60	Yes	No	Cleanse skin for IV insertion.
CMRS	0	1	1	No	No	For crew safety during procedures.
Dilaudid (Hydromorphone) 2mg/mL, 1mL syringe	0	4	18	Yes	Yes	Pain relief.
Ertapenem 1gm	0	1	6	Yes	Yes	Antibiotic
Hot and Cold Pad	0	1	1	No	No	Pain relief.
IV administration set	0	1	3	Yes	Yes	Administration IV fluids
IV Cap	0	1	5	Yes	No	IV administration
IV Catheter (18G, 20G, or 22G)	0	1	14	Yes	Yes	IV fluid administration
IV Fluid 1L (1000mL)	0	2	5	Yes	Yes	IV fluid.
IV Fluid Air Filter	0	1	3	Yes	No	To filter air from IV set
IV pressure infuser	0	1	1	No	No	Applied to IV fluid bags to apply pressure for the administration of fluid.
Lidocaine (Xylocaine) plain 1%, 10mL multi dose vial	0	1	3	Yes	Yes	Anesthetic for ertapenem injection
Needle (23G)	0	3	20	Yes	Yes	For medication administration
Nitrile gloves (large, medium, and small) (pair)	1	1	30	Yes	No	Universal precautions.
Sharps container	0	1	40	No	No	To dispose of medical waste such as used medical needles, scalpels, IV catheters, razors, vials
Suction Tubing - Gastric Tube	0	1	1	Yes	Yes	Decompression of abdomen
Syringe (3cc)	0	3	20	Yes	Yes	For medication administration and for flushing IV lines
Tourniquet	0	1	1	No	No	Used to insert IV catheter.
Tylenol (Acetaminophen) 325 mg	8	0	150	Yes	Yes	Pain relief.
Ultrasound gel (2 packets)	2	2	17	Yes	Yes	Medium for better imagining for ultrasound.
Ultrasound machine	1	1	1	No	Yes	Use for diagnosis
Vicodin HP (Hydrocodone/ Acetaminophen HP) 10 mg/660 mg	0	4	30	Yes	Yes	Pain relief

Resource Comments

Medical management of the best and worst case abdominal wall hernia scenarios were based on terrestrial standards of care (Agency for Healthcare Research and Quality, 2011)(Erickson, 2013)(Nicks, 2013)(Shah, 2013).

Required Resources Level of Evidence (LOE)

The IMM level of evidence appropriate assessment of the quality of the IMM input data. Since IMM incorporates input data from a wide variety of sources including astronaut population, terrestrial or analog populations, and external models, an innovative approach to assess the quality of input data was required. Information obtained from the astronaut population and/or space flight is the more relevant so it is assigned the highest level of evidence and less relevant data sources are assigned a lower level of evidence.

Citation	LOE Value	LOE Category
Agency for Healthcare Research and Quality, 2011	3	Resources
Erickson, 2013	3	Resources
Nicks, 2013	3	Resources
Shah, 2013	3	Resources

Level Of Evidence

Input Data	LOE Average
Incidence	4
Functional Impairment	3
Best Case / Worst Case	4
EVAC / LOCL	4
Resources	3
QUALITY OF EVIDENCE	**3.6**

Description	Range
Excellent	1-2
Good	2.1-3
Fair	3.1-4
Poor	4.1-5

Reference List

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