Barotrauma (ear/sinus block) Cliff

Branch Baseline

Pressure changes result in a variety of symptoms and disorders in closed body cavities, such as ears and sinuses. These symptoms, which are usually temporary, may occur during space flight and they are not related to decompression sickness**.** (Hamilton, 2001) Exposure to decreasing ambient pressures causes the gas present in body cavities to expand. Essential conditions for barotrauma include a gas containing enclosed space and ambient pressure that overcomes the capacity of the enclosed space to equalize the change in atmospheric pressure. Sinus and Ear barotrauma are trapped gas disorders causing physiological effects.(Clark, 2008)

Sinus barotrauma

The paranasal sinuses are air filled, relatively rigid, bony cavities lined with mucous membranes that connect with the nose by the ostia. If the ostia or sinus openings are obstructed pressure equalization becomes difficult or impossible. Unless the pressure is equalized during pressure excursions, extreme pain may result. In about 90% of cases pain develops during repressurization hence for space flight operations is more likely following an EVA repressurization from a suit pressure of 4.3 psi to 14.7 psi cabin atmosphere pressure. During depressurization the expanding air forces its way past the obstruction. While during repressurization the relative negative pressure within the sinus cavities may lock the natural ostia resulting in barotrauma. Sinus blocks among aviators most often occur in the frontal sinus (from 70%) followed by maxillary sinus (to 30%). Sinus problems are preventable by performing an equalization maneuver, e.g. Valsalva maneuver. (Clark, 2008)

Ear barotrauma

The Eustachian tube (ET) connects the middle ear with the nasopharynx. The tympanic end of the ET is bony and usually open, whereas the pharyngeal end is cartilaginous, and closed when relaxed. Opening of the ET occurs during swallowing, chewing or yawning and by direct air pressure. The most common cause of acute dysfunction is edema or tissue hyperthrophy from infection, inflammation or allergy. Gravity affects the nasopharynx soft tissues surrounding the membranous ET. In space ET function may be compromised by head congestion from cephalad fluid shifts. Once fluid shifts associated with early space adaptation have resolved, ET function should not be adversely affected. Symptoms of ET dysfunction are fullness in the ear, mild intermittent discomfort or pain, and a mild decrease in hearing. Symptoms of ear block are the same plus dizziness or tinnitus. Astronauts have used the sensation of ear popping as a subjective measure of pressure changes. Pressure differentials as low as 0.6 psi have been shown to cause minor barotrauma. Static acoustic impedance tympanometry may confirm barotrauma after flight but it has not been useful in forecasting damage prior to exposure. (Clark, 2008)

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:	In-flight
Space Adaptation:	No
Incidence Type:	Rate

Distribution Data	
Incidence:	Gamma
Occurrence:	Poisson

Data Characteristics	
Events:	48
Person Years:	45.49
Space Flight Incidence Rate (Events / Person Years):	48 / 45.49 = 1.05517696196966

Incidence Comments

The incidence for the model is based on space flight data. (Walton, 2010). All events were ear, none sinus barotrauma. By gender, there have been 5 cases for female and 26 for male crew members. Of note, symptoms of barotrauma may be similar to otitis media. Events included here as barotrauma, have not been included in the Otitis Media CliFF.

Appearance of the tympanic membrane in barotrauma may be classified by the Teed Scale. For long duration space flight, over 30 days, the crew medical officer is trained to perform ear examinations prior to EVA. Classification of sinus barotrauma is based on the Weissman Scale. For further description of both scales refer to the CliFF Appendices.

The incidence data was updated to integrate the Real World System observed events including the person at risk from our validation data set. There was 6 ISS and 11 STS events added. Also 18.17 person years was added. This data set included the remaining Shuttle missions and ISS Expedition 31/32 through Expedition 39/40 (Saile, 2017).

Updated the Person-Years based on the revised real world system integrated incidence data. The integrated person years changed from 18.17 to 18.13 so the conditions person years changed from 45.53 to 45.49(Saile L., 2017)

Information Regarding Prevention

Selection criteria

Disqualifying conditions in the Nose, Sinuses, Mouth, and Throat category, include deviation of the nasal septum, enlarged turbinates, or other obstructions to ventilation that significantly restrict nasal breathing, unless medically or surgically corrected with normal function restored; chronic or uncomplicated rhinitis of any cause that may interfere with the performance of duties, nasal polyps or a history of nasal polyps; chronic sinusitis (greater than 3 months), unless surgically or medically treated with no evidence of recurrence. In the ears category: chronic otitis media, suppurative or serous; persistent perforation of the tympanic membrane (International Space Station Program, 2009).

Other

Because the ambient spacecraft atmospheric pressure changes regularly in the course of mission operations, otitis media suspected during space flight must be aggressively treated with decongestants and antibiotics (Marshburn, 2008).

Astronauts get routine training in the recognition and prevention of barotrauma affecting the ears and sinuses during underwater EVA training at Neutral Buoyancy Laboratory (NBL) (Williams, 2003).

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
Walton, 2010	1	Incidence
Saile L., 2017	1	Incidence

Alternative Incidence Data

A retrospective review (DeGroot, 2003) of 23,656 records over a 33 years period, 1969 to 2002, found 296 adverse reactions to simulated altitude. Incidence was calculated with number of reactions per 100 as numerator and number of exposures as denominator. Incidence expressed as reactions for 100 exposures was 0.93 ear block and 0.14 sinus block. Altitude was 8,900 meters (29,200 ft).

A review of published articles by Weitzel et al. reported that although there are few scientific studies on this subject, the pathophysiology and physics of this condition are very clearly understood. Patients presenting before flight with an upper respiratory infection are at risk for aerosinusitis. Sinus barotrauma, or aerosinusitis, is four to six times less common than middle ear barotrauma. Because the maximal pressure differential sustained on a commercial flight is 200 mmHg, severe cases of sinus barotrauma are not reported with civilian air travel. The frontal sinus is most commonly affected (70 – 80%), followed by the maxillary sinus (19 – 29%). There is about a 10% incidence of overlap between frontal and maxillary sinus barotrauma. (Weitzel, 2008)

Morgagni reviewed records of altitude chambers used for training aircrews, regarding 1254 individuals who were trained from 2003 to 2009. After the first 3 subjects, the maximum altitude of the highest training profile was limited to 43,000 ft (13,106.4 m) instead of 45,000 ft (13,716 m) and, after the first 327 subjects; a clinical evaluation of each trainee was performed by an otolaryngologist before altitude exposure. The evaluation included otoscopy and tympanometry and subjects with abnormal results were not cleared for altitude exposure. Subjects were grouped by having undergone the highest profile before (3 subjects) or after altitude restriction (8 subjects) and received clinical selection, pre-chamber clinical selection (PCS) group, 927 subjects or not, control group, 327 subjects. Total adverse effects (overall incidence 2.6% or 32 events, 21 in the PCS group (2.3%) and 11 in the control group (3.4%). The difference between groups was not significant. Adverse effects included **19 cases of acute barotitis** (19/1241) or 1.5% incidence, 1 case of DCS (0.08%), and 4 cases of syncope (0.3%). By group, the incidence of barotitis was 1.1% in the PCS group(10/918) and 2.8% in the control group (9/323). The altitude restriction was ineffective in preventing both barotrauma and DCS. The author concluded that the incidence of adverse effects in the subjects was low and pre-chamber clinical selection appeared to be effective in reducing the risk of barotitis. (Morgagni, 2010)

A survey in Denmark reported the average number of upper respiratory infections (URI) per year was 1.6 (range 0 – 8), whereas the number of episodes of sinusitis per pilot year of flying experience was 0.0314 (range 0 – 0.528). 948 commercial pilots participated in the survey over 6 months. The pilots reported an accumulated number of ear barotraumas of 811 cases, corresponding to 0.0410 episodes per pilot year of flying experience (range 0 – 2.40). There were 37.6% (356/948) who had experienced 1 or more ear barotraumas (range 1 – 50). Total number of sinus barotraumas was 321 cases, corresponding to 19.5% (185/948) of the pilots having experienced 1 or more sinus barotraumas (range 1 – 15). For 7.1%, reported signs of ENT barotrauma started during climb, while only 2.0% reported onset during level flight (cruise). As many as 90.9% reported onset of barotrauma during descent. The average cabin altitude for the onset of symptoms of barotrauma was 6163 ft (range 0 – 10,000 ft).(Rosenkvist, 2008)

Berger identified 91 cases of acute perforation of the ear drum, caused by non-explosive blast injury. Sixty cases were caused by a slap or a fist, 13 patients suffered sport accidents, mostly in ball games, and 18 patients were injured during swimming and water sports activities. The common symptoms were hearing loss, earache, tinnitus, vertigo and otorrhea. A spontaneous closure of the perforation with a conservative management approach was observed in 94.8 per cent of the patients. A high tone sensorineural hearing loss was detected in only 20 per cent of the patients. (Berger, 1994)

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 %: 97.96 - 100)	100	0.25	0 - 16	0 - 84 - 168	0	0	0
ISS-based Treatment (worst case scenario %: 0 - 2.04)	100	0.25	2 - 38	168 - 588 - 1008	0 - 16	0	0
Untreated Best Case	0	0	2 - 38	0 - 84 - 168	0 - 16	0	0
Untreated Worst Case	0	0	18 - 59	168 - 588 - 1008	2 - 59	5 - 20	0

[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

Best case scenario definition: is mild barotrauma consisting to no or minimal pain, fullness in the ears, that responds to analgesics and decongestants.

Worst Case scenario definition: is moderate to severe barotrauma, including symptoms of significant pain, hearing loss, vertigo, nausea, dizziness, and/or ear canal hemorrhage or epistaxis.

Percentages of how often best versus worst case scenarios occur based on the Real World Systems data there were no worst cases so to integrate this data into the BC/WC percentage the algorithm developed with the original data set was used for all the medical events in both data sets. Therefore, if the next case is a worst case we would 1/49 or 2% of cases as worst cases. If the next case is best case, we would have 49/49 or 100%. Thus the percentage forworst case is 0-2% (Saile L., 2017)

Best Case Comments

Barotrauma (ear/sinus block) functional impairments (FI) calculation follows the IMM mild non-space adaptation template. Barotrauma is not listed in the AMA Guides for permanent impairment. By related symptomatology and location, we are using Vestibular Disorders, based on Table 11-4, p 258. (American Medical Association, 2008) and Complex Regional Pain (UEI) is based on Table 15-26, p.454. (American Medical Association, 2008)The CRPS (UEI) ratings are then converted to percentage of Whole Person Impairment (WPI), which are based on Table 15-1, p 385 (American Medical Association, 2008). Combined FI ratings are calculated combining Vestibular disorders FI and Whole Body Impairment using the Combined Values Chart as indicated in Appendix A, pp 604-606 (American Medical Association, 2008). For further description of gradings refer to the CliFF Appendix.

By definition in Clinical Phase I, FI is 100%. Duration to follow procedures specified in ISS checklist, i.e. ear, nose and throat examination is estimated to be 15 minutes. During Clinical Phase II, FI is estimated in 0 to 16%. Duration is estimated in 0 to 168 hours or 7 days based on current standards of care for aerosinusitis (Weitzel, 2008). No recent published data on otic barotrauma was found. Symptoms resolve spontaneously. The recommended waiting period is 2 to 7 days. (Clark, 2008) In Clinical Phase III, by definition, full recovery is expected. and estimated FI is 0%. By definition EVAC and LOCL are not expected for the best case scenario. Barotrauma could be classified as a Class I Medical Event with no mission impact, or a Class IIa, manageable with the HMS and not likely to require evacuation or affect mission duration. (Johnston, 2008)

Worst Case Comments

Barotrauma (ear/sinus block) functional impairments (FI) calculation follows the IMM mild non-space adaptation template. Barotrauma is not listed in the AMA Guides for permanent impairment. By related symptomatology and location, we are using Vestibular Disorders, based on Table 11-4, p 258. (American Medical Association, 2008) and Complex Regional Pain (UEI) is based on Table 15-26, p.454. (American Medical Association, 2008) The CRPS (UEI) ratings are then converted to percentage of Whole Person Impairment (WPI), which are based on Table 15-1, p 385 (American Medical Association, 2008). Combined FI ratings are calculated combining Vestibular disorders FI and Whole Body Impairment using the Combined Values Chart as indicated in Appendix A, pp 604-606 (American Medical Association, 2008). For further description of gradings refer to the CliFF Appendix.

By definition in Clinical Phase I, FI is 100%. Duration to follow procedures specified in ISS checklist, i.e. ear and nose exam is estimated to be 15 minutes. During Clinical Phase II, FI is estimated at 2 to 38%. Duration is estimated in 168 to 1008 hours, 7 to 42 days, or 1 to 6 weeks. For sinus barotrauma symptoms resolve spontaneously; recovery time may extend from 1-2 weeks up to 6 weeks (Weitzel, 2008); (Smith, 1972). For otic barotrauma, including the recommended waiting time for spontaneous resolution is 2-3 weeks (Clark, 2008)In Clinical Phase III, barotrauma may recover or improve. FI is estimated at 0 to 16%. By definition EVAC and LOCL are not expected for the worst case scenario. Barotrauma could be classified as a Class I Medical Event with no mission impact, or a Class IIa, manageable with the HMS and not likely to require evacuation or affect mission duration (Johnston, 2008).

Untreated Best Case Comments

Barotrauma (ear/sinus block) functional impairments (FI) calculation follows the IMM mild non space adaptation template. Barotrauma is not listed in the AMA Guides for permanent impairment. By related symptomatology and location, we are using Vestibular Disorders, based on Table 11-4, p 258. (American Medical Association, 2008) and Complex Regional Pain (UEI) is based on Table 15-26, p.454. (American Medical Association, 2008)The CRPS (UEI) ratings are then converted to percentage of Whole Person Impairment (WPI), which are based on Table 15-1, p 385 (American Medical Association, 2008). Combined FI ratings are calculated combining Vestibular disorders FI and Whole Body Impairment using the Combined Values Chart as indicated in Appendix A, pp 604-606 (American Medical Association, 2008). For further description of gradings refer to the CliFF Appendix.

During Clinical Phase II, FI is estimated to be 2-38%. Duration is 0 to 168 hours, similar to the treated best case scenario. In Clinical Phase III, full recovery or improvement are expected. FI is estimated at 0 to 16%. By definition, EVAC and LOCL are not expected.

Untreated Worst Case Comments

Barotrauma (ear/sinus block) functional impairments (FI) calculation follows the IMM mild non space adaptation template. Barotrauma is not listed in the AMA Guides for permanent impairment. By related symptomatology and location, we are using Vestibular Disorders, based on Table 11-4, p 258. (American Medical Association, 2008) and Complex Regional Pain (UEI) is based on Table 15-26, p.454. (American Medical Association, 2008) The CRPS (UEI) ratings are then converted to percentage of Whole Person Impairment (WPI), which are based on Table 15-1, p 385 (American Medical Association, 2008). Combined FI ratings are calculated combining Vestibular disorders FI and Whole Body Impairment using the Combined Values Chart as indicated in Appendix A, pp 604-606 (American Medical Association, 2008). For further description of gradings refer to the CliFF Appendix.

During Clinical Phase II, FI is estimated to be 18 to 59%. Duration is estimated in 168 to 1008 hours, 7 to 42 days, or 1 to 6 weeks, similar to the treated worst case scenario. In Clinical Phase III, symptoms may or may not improve. FI is estimated at 2 to 59%. Natural history of untreated otitis media (Rosenfeld, 2003) found that 59% of cases with effusion resolved by 1 month, and 74% resolved by 3 months. This data is based on children. Most tympanic membrane perforations heal spontaneously. There is little or no evidence suggesting that diagnosis or management for adults differ from children. (Tintinalli, 2004). Review of the literature did not yield incidence by level of severity or pain. EVAC may be necessary for the cases which do not resolve and when intractable pain and/or perforation may cause hearing loss. Based on Berger's study (Berger, 1994) we are estimating EVAC at 5 to 20%; i.e. 5% of failure to heal spontaneously as the lower limit, and 20% of hearing loss for the higher limit. LOCL is not expected.

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
American Medical Association, 2008	3	FI
American Medical Association, 2008	3	FI
American Medical Association, 2008	3	FI
Rosenfeld, 2003	4	EVAC
Berger, 1994	4	EVAC
Saile L., 2017	1	BCWC

Additional Comments

Files et al searched the U.S. Navy and U.S. Air Force Safety Centers databases for decompression incidents during FY1981–FY2003. A total of 1055 incidents were analyzed as to the cause, speed of onset, and adverse health effects (hypoxia, barotrauma, DCS, or any combination of these). Of the 1055 incidents, only 350 (33.2%) involved adverse health effects. Hypoxia occurred in 221 incidents, DCS in 83, and barotrauma in 71. Many incidents involved more than one symptom. 16.3% were barotrauma alone, 3.1% combined with hypoxia, 0.6% combined with DCS, and 0.3 combined with hypoxia and DCS. Total percentage reported was 19.49%. These data are reported in terms of depressurization incidents, not number of people injured (“cases”). Most incidents involved only one person, but a few of the 350 incidents involved injury to several individuals. (Files, 2005)

Incidents of sinus versus ear barotrauma have not been reported separately. A more accurate figure could have been obtained by using the total number of incidents as the denominator (71/1055) 6.73%.

The Resource Table (RT)

Resource	Units Required Best Case	Units Required Worst Case	Units Available At Start Of Mission	Consumable	Essential	Rationale
Afrin (Oxymetazoline) 0.05% 15mL bottle	0.6	0.6	10	Yes	Yes	Relief of nasal congestion (topical)
Disposable Otoscope Specula (regular, small)	2	2	90	Yes	No	For use with otoscope for exams
Motrin (Ibuprofen) 400mg	0	40	400	Yes	Yes	Relief of Pain
Otoscope (Head, Handle, and USB cable)	1	1	1	No	Yes	Light source for nasal, oral, aural, and eye exams.
Phenergan (Promethazine tablet) 25 mg	0	6	100	Yes	Yes	For nausea

Resource Comments

All resources for barotrauma treatment are included in the ISS medical checklist (MOD, 2011). The checklist describes procedures for diagnosing and treating ear block and sinus block.

There are no terrestrial guidelines for in-flight barotrauma. Clinical guidelines cited in the literature apply to diving or hyperbaric chambers.

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
NASA Mission Operations Directorate (MOD), 2011	2	Resources

Level Of Evidence

Input Data	LOE Average
Incidence	1
Functional Impairment	3
Best Case / Worst Case	1
EVAC / LOCL	4
Resources	2
QUALITY OF EVIDENCE	**2.2**

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

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