Prospective, Observational, Multicenter Study on Incidence, Risk factors and Outcome in Intra-abdominal Hypertension (IROI Study)

Study protocol

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Template as developed by the

Clinical Trials Working Group

Of the

World Society of the Abdominal Compartment Syndrome

Note.
1. This template serves as a guide for setting up a study protocol. Parts highlighted in gray are examples or give extra details regarding the required information.
2. The first part of this template, (Part A, p. 2-3) is the synopsis of the study, the full protocol start on page 4 (part B). Some parts from the synopsis can be copied and pasted in the corresponding parts of the full protocol, with room for additional information or details when considered necessary.

PART A. Summary of the study

Principal investigator(s):

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Study centers and number of patients planned: 25 centers, 500 patients.

Study sites:

Intensive Care Units with

- at least 8 beds
- previous experience with intra-abdominal pressure (IAP) monitoring

Patient mix:

- preferably mixed patient population
- specialized centres (only cardio- or neurosurgery) may provide one third of the total study population at maximum

Potential sites will be identified based on the survey performed by the Clinical Trials Working Group (CTWG) of WSACS in 2011. The final list of study sites will be approved by the CTWG.

Study participants (Name plus affiliation, listed alphabetically):

To be advised

Study period

Enrolment of first patient: TBA

Estimated date of last patient in study: TBA

Every site will start enrolment independently of other sites. Duration of enrolment will be two weeks or at least 20 consecutive patients from each site. Follow up period will be until discharge from ICU or until two weeks (14 days) after enrolment. Rationale is that after two weeks in ICU new cases of intra-abdominal hypertension (IAH) are rare (< 2% of all IAH

cases in a previous single-centre study (1)). Patients readmitted within one week after ICU discharge, will not be included newly.

Objectives

Primary objective

- To describe the incidence and risk factors of IAH in critically ill patients.

Secondary objective(s)

- To describe the outcome of IAH in critically ill patients.
- To describe the incidence, risk factors and outcome of abdominal compartment syndrome (ACS) in critically ill patients.
- Formulating a screening tool that aims to predict critically ill patients to have or develop IAH.

Study design

Prospective, observational, multicenter study

Patient population

Consecutive adult patients, admitted to the participating ICU-s during the study period.

Duration of the study period

Enrolment of the patients for two weeks or at least 20 consecutive patients for each site.

For the individual patient

1. Study period until discharge from ICU or 14 days
2. Follow-up period of 28 days and 90 days

Endpoints

Primary endpoint

Development of intra-abdominal hypertension (IAH)

Secondary endpoints

Development of ACS

ICU mortality

Length of stay (LOS) in ICU

Length of Hospital stay

28 day mortality and 90 day mortality

Potential risk factors associated with a) presence or development of IAH, b) presence or development of ACS, c) outcome in patients with IAH and/or ACS

PART B. Study protocol

1. INTRODUCTION

1.1 Background.

Intra-abdominal hypertension (IAH) is defined as a sustained or repeated intra-abdominal pressure (IAP) equal or greater than 12 mmHg and is thought to be an important contributor to adverse outcome in critically ill patients. Around one fourth of all ICU patients and one third of mechanically ventilated (MV) patients may develop IAH during their ICU stay (1,2,3). Incidence of IAH has been reported between 18 and 81% depending mainly on cut-off values of IAP and selection criteria of included patients (2).

The risk factors proposed by World Society on Abdominal Compartment Syndrome (WSACS) are based on possible pathophysiological mechanisms according to expert opinion (4), but the evidence supporting these criteria is scarce. In a single-centre study on mechanically ventilated patients with ICU length of stay greater than 24 hours, a check-list was developed for IAH risk factors (1). This check-list allowed for identification of a small patient group not at risk for IAH in a selected patient population.

Adverse outcomes in patients with IAH have been observed in several studies (5,6,7), but not all studies have confirmed this association (8).

Abdominal compartment syndrome (ACS) is defined as a sustained IAP > 20 mmHg with an onset of new organ failure (4) and has variably been observed in 1-36% of critically ill patients depending on the case mix (1,2,5,9,10). There is greater evidence for adverse outcomes with established ACS but morbidity and mortality rates vary significantly between studies.

1.2. Rationale for the study.

The true incidence and outcome of critically ill patients with IAH and ACS is still unclear due to many factors. Before the 2006 WSACS consensus definitions on IAH and ACS, the cut-off values for IAP used and the study population examined varied considerably between different trials (4).

It is important but difficult to identify the risk factors for IAH/ACS in the critically ill patient on admission or during their ICU stay for several reasons: A) To date there are no ideal screening tools to guide intensivists in selecting which patients require IAP measurement

(**Question A = which patient is likely to have IAH on admission?**). B) Risk factors associated with the development of IAH while in the ICU (**Question B = which patient is likely to develop IAH during their ICU stay?**). C) Identifying risk factors associated with worse outcomes in patients with IAH / ACS in order to develop treatment strategies in such patients.

So far no observational trial has included a large mixed ICU population enrolling all consecutive patients while defining IAH and ACS based on the current guidelines.

2. STUDY OBJECTIVES

Primary objective

To describe the incidence, and identify the risk factors of IAH.

Secondary objectives

To describe the impact of IAH on patient outcomes.

To describe the incidence and impact on outcome, and to identify the risk factors of ACS.

3. STUDY PLAN AND PROCEDURES

3.1. Overall design

This is a prospective observational study, enrolling all consecutive adult patients admitted to the participating ICUs during the study period.

All patients will be enrolled (waived consent or delayed consent as deemed necessary by the local ethics committee) into the study if they are 18 years of age or older and if a bladder catheter is in situ. There are no other inclusion or exclusion criteria for this study.

All patients aged under 18 years and patients in whom IAP measurements are not possible (the reason needs to be documented) will be documented as screening failure.

(see 3.2.3)

Patients will be studied until discharge from the ICU or for two weeks from the date of admission to ICU. Follow-up will be performed on day 28 and day 90 after ICU admission.

The study design will be as follows

Day 0. Screening assessment.

1. Informed consent will be waived due to observational study design or obtained within 48 hours of admission from the subject or patient's next of kin according to local regulations.
2. All adult patients admitted to participating ICUs with a bladder catheter in situ must be enrolled into the study.
3. All patients aged under 18 years, patients in whom IAP measurements are not possible (the reason needs to be documented), or where patients or the patient's next of kin disagree with inclusion into the study (in cases where deemed necessary by the local ethics committee), will be documented as screening failure.

Baseline parameters

1. Gender, age, weight, height, type of admission (elective surgical, emergency surgical, medical), reason for ICU admission, principal pathology, site of surgery (see Appendix), site and severity of infection (see Appendix), lactate, APACHE II score (see Appendix).
2. Possible risk factors (RF) of IAH (laboratory parameters will be documented when available = measured for clinical purposes):
    a. BMI on admission (1,2)
    b. Respiratory
        i. Mechanical ventilation (yes/no, daily) (11)
        ii. PEEP in cmH_2O (the highest, excluding recruitment periods, daily) (1)
        iii. pO_2/FiO_2 ratio (the lowest = SOFA sub-score, daily) (1,2,11)
        iv. Peak and plateau airway pressure (the highest set pressures, excluding coughing or purging peaks, daily) (1)
        v. Dynamic respiratory compliance (the lowest, daily)
    c. Fluid resuscitation / Shock
        i. Fluid resuscitation in L/ 24h crystalloids or colloids (daily) (2,5,7,11)
            1. crystalloids, colloids and blood products will be documented separately
        ii. Transfusion = Units / 24h (daily) (2)
            1. pRBC, FFP and platelets will be documented separately
        iii. Sepsis (yes (with severity grade)/no, daily) (1)
            1. C-reactive protein (CRP)
        iv. Vasopressor / inotrope = presence (yes/no daily) (1,7,11)
            1. Amount of inotropic support in microg/min (highest dosage, daily) = SOFA
        v. Coagulation (2,5)
            1. INR (highest value, daily if available)
            2. Platelets (lowest value = SOFA sub-score, daily)
            3. APTT (highest value, daily if available)
        vi. Acidosis (lowest pH, daily) (5,11)
        vii. Blood lactate (highest value, daily if available)
    d. Fluid retention / Renal
        i. Urine output (ml/day) (1,2,11)

ii. Creatinine (highest value = SOFA sub-score daily) (1,2,11)
iii. CVP in mmHg (lowest and highest value daily) (1)

e. Abdominal pathology and/or symptomatology
   i. Pancreatitis (defined (12) as 2 out of 3 of the following: abdominal pain suggestive of pancreatitis, serum amylase and lipase levels > 3 times normal, and characteristic findings on CT, MRI or US) (1,13,14,15)
   ii. Hepatic failure (defined as INR > 1.5 and mental alterations (16) related to acute or chronic liver disease) or cirrhosis with ascites (clinically or radiologically), on admission (1,5,17,18)
      1. Bilirubin (highest value = SOFA sub-score, daily)
      2. Albumin (lowest value, daily)
   iii. AAA repair (elective vs. emergency, endovascular vs. open) (on admission) (19,20)
   iv. Laparotomy (yes/no, daily) (1,2,7,9)
   v. Gastrointestinal bleeding (yes/no, daily) (macroscopic evident blood in vomitus, nasogastric aspirates or stool) (1)
   vi. Hemoperitoneum or hemoretroperitoneum (yes/no, daily) (5)
   vii. Ileus (5,11)
      1. abdominal distension (yes/no, daily)
      2. absence of bowel sounds (yes/no, daily)
   viii. Gastroparesis
      1. gastric residuals in ml/24h (daily)
      2. failure of enteral feeding based on subjective decision when implemented enteral feeding had to be stopped or markedly reduced (below 20% of planned amount) for any clinical reason (high gastric residuals, vomiting, severe diarrhoea, abdominal distension etc) (3)

f. Other pathologies
   i. Burns: burn size in % of total body surface area on admission (21,22)

g. Other
   i. APACHE II score (23) on admission (1,3,11)
   ii. GCS = SOFA sub-score, daily
   iii. Total SOFA score (24), daily (1,3,11)

Day 1 to end of study period

Data collection.

Intra-abdominal pressure (IAP):

IAP will be documented at least once every 8 hrs throughout the study period.

When intermittent measurements are performed they can either be with the modified Kron's method (instillation of maximal 25 ml) or with the Foley Manometer method. Pressure measurement technique should be in accordance with the Guidelines of World Society on Abdominal Compartment Syndrome (4).

Three measured IAP values daily are collected until ICU discharge or for 14 days. The nearest MAP to the measured IAP will also be collected (maximal and mean IAP will be calculated). Admission day includes minimum 8 hours and maximum 32 hours, ending with the begin of the next chart day. Following ICU days are defined as chart days.

Abdominal perfusion pressure will be calculated as APP = MAP – IAP.

Intra-abdominal hypertension (IAH) is defined as sustained or repeated IAP ≥ 12mmHg.

Abdominal compartment syndrome (ACS) is defined as sustained IAP > 20mmHg associated with new organ dysfunction/failure (4)**. New organ dysfunction/failure** will be documented.

Presence of risk factors for IAH additional to admission diagnosis (see Baseline parameters) will be documented daily. Laboratory parameters will be documented when available = if measured for clinical purposes.

Follow-up period

On day 90 after ICU admission survival data, ICU and hospital length of stay, duration of mechanical ventilation and time of definitive closure in case of laparotomy.

3.2. Selection of the study population

3.2.1. Study selection record

The investigator is requested to keep a record of all patients admitted to the ICU during the study period.

3.2.2. Inclusion criteria.

For inclusion in the study, subjects must fulfil all of the following criteria:

- Age 18 years or older
- Bladder catheter in situ
- No contraindications for IAP measurements via urinary bladder catheter

3.2.3. Exclusion criteria.

Any of the following is regarded as a criterion for exclusion from the study:

- Age below 18 years
- No bladder catheter in situ
- In case of delayed consent (depending on local ethics committee) objections by the patient or the relative to use observational data

3.2.4. Sample size calculation

Since this is an epidemiologic study no sample size calculation will be performed. Previous observational trials included 83 (11), 97 {(2), 265 (5), 257 (7), and 563 (1).
We hypothesize the incidence of IAH is around 20%. We estimate that we would require at least 500 patients (resulting in about100 patients with IAH) to describe the risk factors. Furthermore, we estimate to require 25 centres with an average of 20 patients per centre.

3.3. Rationale for the study design

Prospective, multicenter study is the only opportunity to identify the incidence and risk factors of IAH in ICU patients.

4. STUDY MEASUREMENTS AND ENDPOINTS

4.1. Primary endpoint

Development of intra-abdominal hypertension (IAH)

4.2. Screening and demographic measurements

The following data will be recorded at baseline, i.e. on admission to ICU.

- Gender
- Age
- Body weight and height
- Type of admission (Appendix)
- Reason for ICU admission (Appendix)
- Principal pathology (Appendix)
- Site of surgery (Appendix)
- Site and severity of infection (Appendix)
- Acute Physiology and Chronic Health Evaluation (APACHE) II score (see Appendix) (23). Worst score in first 24 hrs after ICU admission will be documented.
- Possible risk factors for IAH

In all patients not included in the study (screening failure) gender, age, type of admission (medical, elective surgical or emergency surgical), the reason for ICU admission, principal pathology, and the reason for exclusion will be documented.

4.3. Measurements during study period

- Intra-abdominal pressure (IAP)

IAP will be documented once every 8 hrs throughout the study period.

Mean and maximum of all daily IAP measurements will be calculated retrospectively

- Presence or absence of abdominal compartment syndrome (yes/no, primary/secondary) during the respective study day (new organ failure will need to be specified).
- Possible risk factors for IAH.

4.4. Primary endpoints and method of assessment

- The total incidence (number and percentage of patients) of IAH will be identified.

4.5. Secondary endpoints and methods of assessment.

- The total incidence of ACS will be identified
- Total ICU mortality and mortality at 28 and 90 days (number and percentage of patients) will be identified
- Total ICU mortality and mortality at 28 and 90 days in groups with and without IAH, as well as with and without ACS will be compared using Chi-Square test
- ICU LOS (days, median) in total and in sub-groups (no IAH vs. IAH; no ACS vs. ACS) will be identified.
- Multiple logistic regression analyses will be performed to identify independent risk factors of IAH and ACS. Risk factors on admission and during the ICU stay will be assessed both together and separately.

    RF of having or developing IAH are to be identified

    RF of patients with IAH resulting in adverse outcome will be identified

5. DATA MANAGEMENT AND STATISTICS

Electronic case report forms will be provided for the recording of the data.

Statistical analysis.

A general linear model will be used for identification of risk factors of IAH.

6. MANAGEMENT GUIDELINE OF PATIENTS WITH DIAGNOSED IAH / ACS

When a patient has been diagnosed with IAH / ACS we recommend medical and surgical management as outlined by the WSACS guidelines published in 2007 {Cheatham et al., 2007, Intensive Care Med, 33, 951-62} (see attached a) general and b) medical management guidelines when caring for patients with IAH / ACS in appendix). Such a protocolled approach including serially measuring IAP and medically and/or surgically treating critically ill patients with IAH / ACS has been associated with improved outcome {Cheatham and Safcsak, 2010, Crit Care Med, 38, 402-7} {Cordemans et al., 2012, Ann Intensive Care, 2 Suppl 1, S15}.

Where primary IAH / ACS is suspected based on a thorough clinical review any combination of abdominal ultrasound, abdominal computer tomography and surgical review should be considered to diagnose and potentially treat any underlying abdominal pathology. Treatment of a primary IAH / ACS will include any combination of medical treatment options and radiological or surgical interventions.

Medical management options will be considered and applied where deemed beneficial to both patients with primary and secondary IAH / ACS. Medical management options include: a) evacuation of intra-luminal contents, b) evacuation of intra-abdominal space occupying lesions, c) improving abdominal wall compliance, d) optimise fluid administration, e) optimise systemic / regional perfusion. Medical management should be considered as a stepped approach with the more aggressive management reserved for patients with having a higher grade of IAH.

If the patient has a life-threating ACS (IAP > 25 mmHg) abdominal decompression is recommended to avoid death.

7. REFERENCES.

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APPENDIX

DEFINITIONS

Type of admission will be recorded as follows:

1. medical – no surgery in 4 weeks preceding ICU admission
2. elective surgical – surgery in 4 weeks preceding admission, scheduled > 24 hrs in advance
3. emergency surgical - surgery in 4 weeks preceding admission, scheduled within 24 hrs of operation

Intra-abdominal hypertension (IAH) is defined as sustained IAP ≥ 12mmHg

Abdominal Compartment Syndrome (ACS) is defined as sustained IAP > 20mmHg with new organ dysfunction/failure.

Severity of infection will be evaluated according to the Surviving Sepsis Guidelines/Definitions as follows:

1. no sepsis – no suspected or confirmed infection
2. sepsis – suspected or confirmed infection with the symptoms of systemic inflammatory reaction (2 or more of the following: temp >38°C; heart rate >90/min; respiratory rate >20/min or $PaCO_2$ >32 mmHg; WBC count >12.000 or <4000/µL or >10% of bands)
3. severe sepsis – sepsis with at least 1 organ failure
4. septic shock – severe sepsis with hypotension sustained despite adequate fluid resuscitation

CODES

Reason for ICU admission

1. Neurological deterioration/coma
2. Respiratory failure
3. Cardiac failure
4. Renal failure
5. Metabolic disorder
6. Multiple organ failure
7. Postoperative mechanical ventilation
8. Shock
9. Other

In case of shock the form of shock needs to be specified (several concomitant forms possible):

1. Septic shock
2. Cardiogenic shock
3. Hemorrhagic shock
4. Hypovolemic shock
5. Anaphylactic shock
6. Mixed

Principal pathology

1. Neurological pathology
2. Pulmonary pathology
3. Cardiac pathology
4. Aortic pathology
5. Peripheral vascular pathology
6. Hepatic pathology
7. Renal pathology
8. Pancreatic pathology
9. Gastrointestinal pathology
10. Polytrauma with abdominal lesion
11. Polytrauma without abdominal lesion
12. Burns, size _____ % of body surface area
13. Other

Site of surgery

1. Neurosurgery
2. Thoracic (incl thoracic aorta)
3. Cardiac
4. Abdominal aortic
5. Hepatic
6. Renal- urinary tract
7. Pancreatic
8. Gastrointestinal
9. Orthopedic
10. Peripheral vascular
11. Other

Sequential Organ Failure Assessment Score (SOFA)

Add the points for each of the six variables to determine the total SOFA score.

Variable	0	1	2	3	4
PaO_2/FiO_2 (mmHg)	> 400	≤ 400	≤ 300	≤ 200	≤ 100
Platelets ($10^3/\mu L$)	> 150	≤ 150	≤ 100	≤ 50	≤ 20
Bilirubin (mg/dL) [micromol/L]	< 1.2 [< 20]	1.2-1.9 [20 – 33]	2.0-5.9 [34 - 101]	6.0-11.9 [102 - 204]	> 12 [> 204]
Hypotension	None	MAP < 70 mmHg	Dopamine ≤ 5	Dopamine > 5 Dobutamine > 5 Dopexamine > 5 Epinephrine ≤ 0.1 Norepinephrine ≤ 0.1	Dopamine > 15 Dobutamine > 15 Dopexamine > 15 Epinephrine> 0.1 Norepinephrine> 0.1 Vasopressin (any dose)
Glascow Coma Scale	15	13-14	10-12	6-9	< 6
Creatinine (mg/dL) [micromol/L]	< 1.2 [< 110]	1.2-1.9 [110 - 170]	2.0-3.4 [171 -299]	3.5-4.9 [300 - 440]	> 5 [> 440]

APACHE II (Acute Physiology and Chronic Health Evaluation) Score

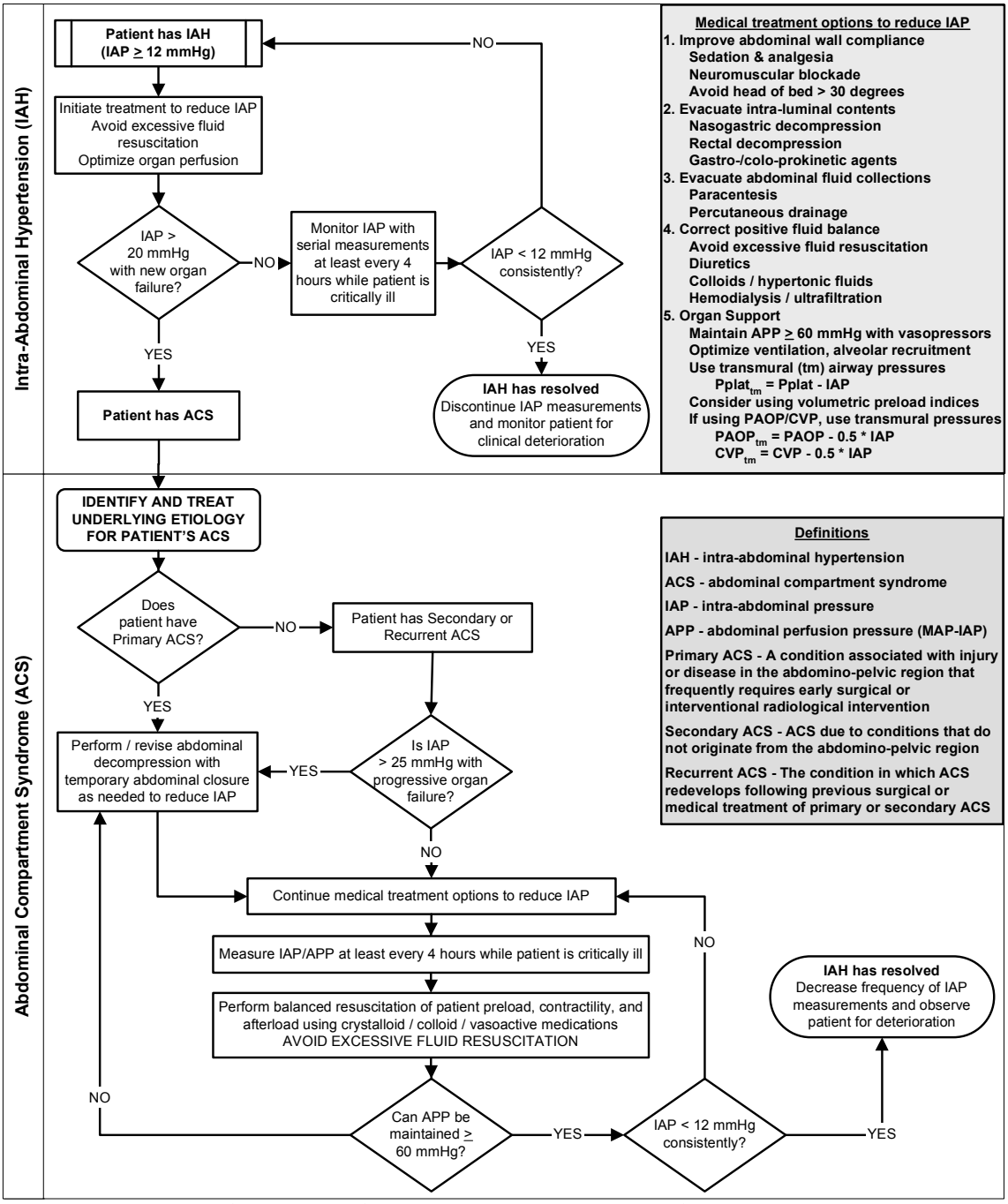
A. Acute Physiology	0	1	2	3	4
Core temperature (º C)	36.0-38.4	34.0-35.9 38,5-38,9	32.0-33.9	30.0-31.9 39,0-40,9	<= 29.9 >= 41,0
Mean Arterial Pressure (mmHg)	70-109		50-69 110-129	 130-159	<= 49 >=160
Heart Rate (beats/min)	70-109		55-69 110-139	40-54 140-179	<=39 >=180
Breath Rate (breaths/min)	12-24	10-11 25-34	6-9	 35-49	<=5 >=50
Oxygenation a. If $FiO_2 \geq 0,5$ calculate A-aDO_2=FiO2(713)-$PaCO_2$-PaO_2 b. If $FiO_2 < 0,5$ record PaO_2 (mmHg)	<200 >70	 61-70	200-349	350-499 55-60	>= 500 < 55
Arterial pH	7.33-7.49	 7.50-7.59	7.25-7.32	7.15-7.24 7.60-7.69	< 7.15 >= 7.70
Serum Sodium (mmol/L)	130-149	 150-154	120-129 155-159	111-119 160-179	<= 110 >=180
Serum Potassium (mmol/L)	3.5-5.4	3.0-3.4 5.5-5.9	2.5-2.9	 6.0-6.9	< 2.5 >=7.0
Serum Creatinine (mmol/L)	54-129		<54 130-169	 170-304	 >=305
Haematocrit (%)	30.0-45.9	 46.0-49.9	20.0-29.9 50.0-59.9		< 20 > 60
WBC ($x10^9$/L)	3.0-14.9	 15.0-19.9	1.0-2.9 20.0-39.9		<1.0 >= 40
Glasgow Coma Scale (15 - patient`s score)					

B. Age	points
< 44	0
45-54	2
55-64	3
65-74	5
≥ 75	6
C. Chronic Health	points
Non operative or emergency postoperative	5
Elective postoperative	2

Liver insufficiency	Biopsy proven cirrhosis. Documented portal hypertension, episodes of past upper GI bleeding attributed to portal hypertension. Prior episodes of hepatic failure / encephalopathy / coma.
Cardiovascular insufficiency	NYHA Class IV
Respiratory insufficiency	Documented chronic hypoxia, hypercapnia, secondary polycythemia , severe pulmonary hypertension (> 40 mmHg), or respirator dependency. Chronic restrictive, obstructive or vascular disease resulting in severe exercice restriction, i.e. unable to climb stairs or perform household duties.
Renal insufficiency	Receiving chronic dialysis
Immuno-depression	The patient has received therapy that suppresses resistance to infection e.g. immuno-suppression, chemotherapy, radiation, long term or recent hight dose

General IAH / ACS management guideline

INTRA-ABDOMINAL HYPERTENSION (IAH) / ABDOMINAL COMPARTMENT SYNDROME (ACS) MANAGEMENT ALGORITHM



Adapted from *Intensive Care Medicine* 2006;32(11):1722-1732 & 2007;33(6):951-962

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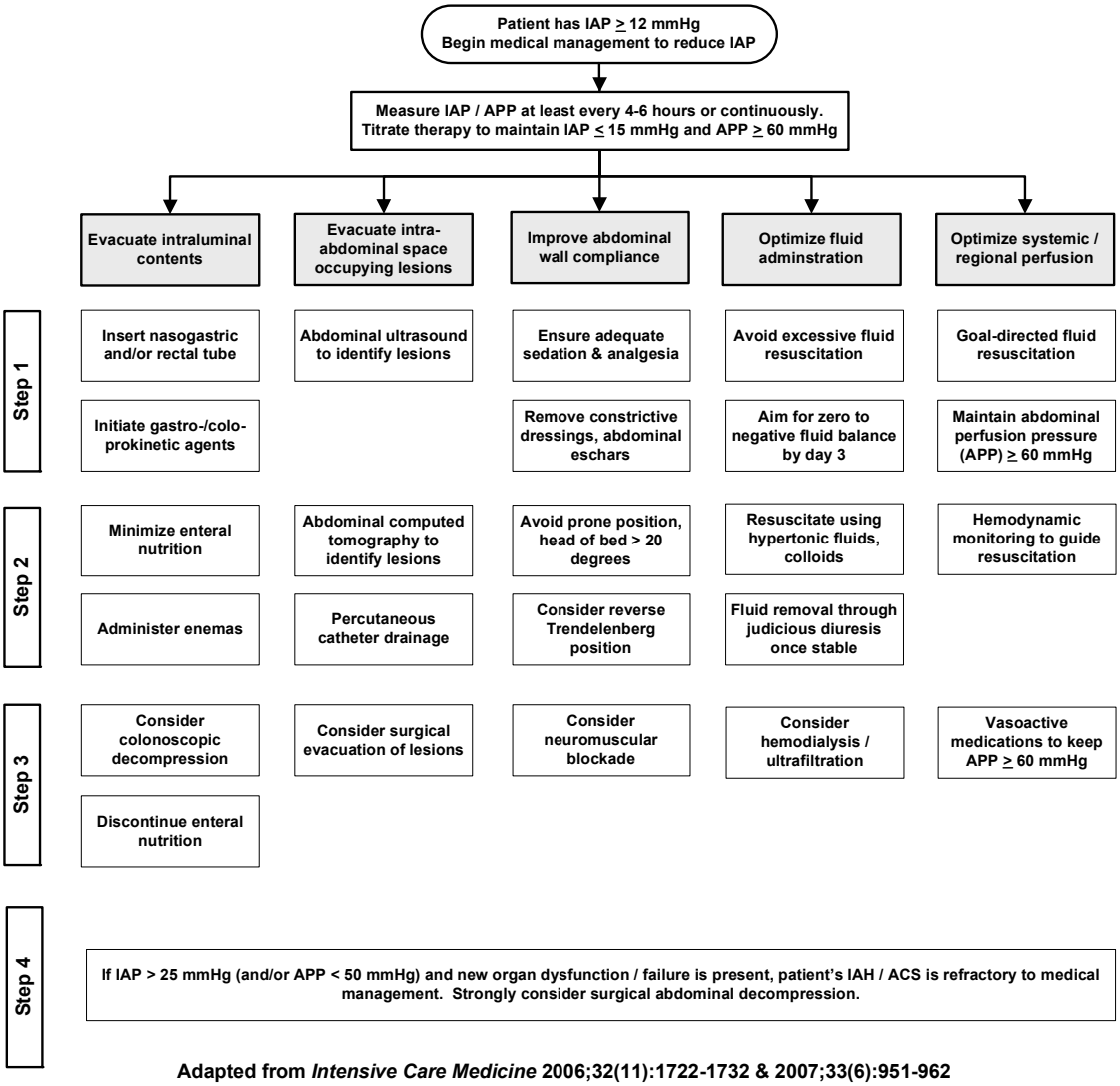
Medical IAH / ACS management guideline

IAH / ACS MEDICAL MANAGEMENT ALGORITHM

- *The choice (and success) of the medical management strategies listed below is strongly related to both the etiology of the patient's IAH / ACS and the patient's clinical situation. The appropriateness of each intervention should always be considered prior to implementing these interventions in any individual patient.*
- *The interventions should be applied in a stepwise fashion until the patient's intra-abdominal pressure (IAP) decreases.*
- *If there is no response to a particular intervention, therapy should be escalated to the next step in the algorithm.*



Adapted from *Intensive Care Medicine* 2006;32(11):1722-1732 & 2007;33(6):951-962

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