

# 0% Mortality in the First Twenty Days Post Operatively after Open Surgical Repair of Ruptured Abdominal Aortic Aneurysms

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#### **Abstract**

**Introduction:** A new combination of both new and older accepted techniques were applied to periand infra renal ruptured abdominal aortic aneurysms.

**Objective:** To cure a disease process with a 48% to 90% surgical mortality and 20% to 30% endovascular surgery mortality. Double blind is an adequately described mortality in the literature.

**Participants:** Fifteen consecutive patients had open surgery resulting in 0% mortality in the first 20 days and 7% mortality at 30 days. The technique and tables showing the demographics, main characteristics of each patient's operative and hospital course and complication of the patient population are included in the main paper. Significant portions of the patient's hospital records are available for reviewers to collaborate with the tables and paper as desired.

**Results:** Fifteen patients had 0 % mortality for 20 days. One patient succumbed to pre-existing pneumonia secondary to muscular dystrophy by 30 days post-operative. No patient died as a direct result of the surgical procedure or as a direct result of the ruptured abdominal aortic aneurysm.

**Conclusion:** While the sample size is small it is very statistically significant p<0.0001. This level of significance is better than required for new drug or medical equipment usage. This technique will require usage at multiple medical centers in order for all surgeons treating this disease to grain confidence in it.

# **OPEN ACCESS**

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#### Introduction

The incidence of ruptured abdominal aortic aneurysms is approximately 3.4/100000 in the general population with a surgical incidence of 31100000 [1]. For patients treated in the USA in 1994, the operative mortality was 68% (4516 deaths/6623 surgeries) per the National Hospital Discharge Survey (CR) data base [1].

In 39 research articles with the lowest mortality utilizing the conventional method of repair of ruptured abdominal aortic aneurysms (CR), there were 8625 deaths/17650 patients with an average mortality of 49% with a range 30 to 90 [2-40]. Other surgical teers at one of the author's hospitals used the CR protocol (drawn from the same population) experienced a 75% mortality over a 7 year period.

The SSHP includes 15 patients with 0% mortality at 20 days (Table 1). Mortality from the surgical repair is usually over after the first 18n days and not the standard 30 days for other surgical procedures. Co-morbid disease processes gradually become the dominant form of morbidity and mortality after the first two weeks and take over all mortality at three weeks. The one death in this series was from pre-operative pneumonia with muscular dystrophy. Prior to the development of the SSHP, the author's mortality on these patients was ~50%.

# **Material**

This report covers 15 consecutive patients treated by the SSHP. These surgeries were performed at four different hospitals with the author as the only surgeon. In one hospital <40 elective abdominal aortic aneurysm were performed/year and in a second hospital no aortic aneurysm repairs were performed/year. Two other hospitals had small active open-heart surgery programs. These forprofit community or district hospitals had no residency programs, were not part of any university system, and had <200 beds.

Table 1: The SSHP includes 15 patients with 0% mortality.

Age/Race/ Sex	Surg. Date	Aneur ysm Size (cm)	PreOpHypo- tension <80 mm	Syncope/ Coma		Cross clamp Infra/Supra	Coumadin INR	Lowest PatientO.R. Temp F	Tube (T)/ Bifurcated (B) Graft	EBL ccs.	PRCs/Cell Saver 250 cc/ Unit	Major Morbidities/ Hospital Days (D)
70/H/M	7/93	15 × 8	yes	no	no	infra	no	93	В		3/3	Post-op carotid endarterectomy/24D
32/C/M	12/	8 × 10	yes	no	no	infra	no	92	Т	1300	4/2	Transient renal failure
33/B/F	4/94		yes	yes	no	infra	no	95	Т	2500	5/4	None/11D
71/C/M	3/97		yes	yes	no	infra	no	96	В	3000	9/2	None/10D
71/C/M	3/97	6 × 6	no	no	no	infra	no	98	Т	350	0/1	None/6D
51/C/M	7/99	11 × 10 × 11 × 11	yes	yes	·no	infra	no	93	В	3500	10/12	DVT/Mediastinal Bleed/ Thoracotomy/Greenfield Filter/34
H/C/M	9/99	10 × 10	yes	yes	yes	infra	no	88	Т	1600	6/6	Respiratory insufficiency./24D
58/C/M	4/01	8 × 10 × 13	yes	yes	no	infra	yes	98	B; Bilat. CIAA	2000	4/3	Duodenal ulcer hemorrhage/ Respiratory Insufficiency/34D
71/C/F	5/01	6×6	no	no	no	infra	yes	97	B; Bilat. CIAA	3000	3/4	Muscular dystrophy/ Rectus muscle hematoma evacuation; Myocardial Infarction; Pulm. sepsis; Died/21D
59/C/M	8/01	10 x 10 x 13	yes	yes	no	infra	yes	96	Т	5500	9/10	Respiratory insufficiency./ Cardiac arrythmlas/19D
33/C/M \1	12/01	10 × 10 × 17	yes	yes	no	infra	yes	97	B; Bilat. CIAA	3000	3/4	Resection pre perforation sigmoid Colon/Respiratory Insufficiency
53/H/F	12/01	7 × 7	yes	yes	yes	infra	no	92	Т	1500	4/2	None/9D
74/C/M	4/02	9 × 8	yes	yes	no	supra	yes; INR3.5	95.9	Т	1200	4/1	Mild ischemic colitis; Atrial fibrillation; Pre-op AVR/CABG &
58/C/M	9/02	7 × 10	O mm. BP	yes	no	infra	no	95	Т	3500	6/5	Acute Tubular Necrosis/30D
78/C/F	11/02	7 × 7	Cardiac	Arrest	yes	infra	no	93	Т	3300	6/7	Renal & Respiratory Failure/A. Fib./450

# **Patient demographics**

The SSHP patients' demographics were compared with a "indirect historic control" (Table 2), of 2,058 patients with a 48 mortality from within the CR group [2,4,15,16,19-21,25,26,32,34,38,40]. The SSHP group had a significantly higher percentage of patients with hypotension, syncope, >80 y/o, and carotid artery/peripheral vascular disease. No patients in this historic meta-analysis had pre-operative diabetes mellitus. Survival rates are given at 45 days for SSHP. Since the early mortality of the SSHP appeared to be 15% vs. 49% in the CR protocols, doing a 1:1 prospective study might not have met ethical standards.

# Aneurysm pathology

Aneurysm size in 14 of the patients varied from 6 cm to 11 cm. in diameter and 8 cm to 15 cm. in length as noted on the pre-operative CT-Scan. 20% of the patients had bilateral common iliac artery aneurysms with the tear extending from the aorta into one of the common iliac artery aneurysms. 7% of the patients had supra-renal extension of the aneurysms.

# **Methods**

All patients and/or their relatives were informed of the risks & benefits of the SSHP, alternative procedures, and signed operative permits. The fifteen specialized SSHP patients were treated as follows:

1. After the diagnosis is determined and if there is a "spark" of life no time is wasted in getting the patient to the operating room. Aneurysm neck position is determined by a very rapid limited non-contrast abdominal C-T exam if the patient is stable enough

to tolerate the exam and no abdominal C-T was done during the diagnostic work-up. No effort is made to determine if the patient will survive surgery.

- Minimal pre-operative volume expansion with crystalloid/ blood is acceptable in the ambulance and/or emergency room to attempt to increase the systolic blood pressure to >60 mm. Hg <80 mm. Hg. if needed to maintain cardiac function. A thready pulse palpable anywhere is acceptable. Patients in the SSHP were not adversely affected by transport distance and/or hypotension as long as they were not over hydrated. Raising blood pressure to "normal" can blow away natures "patch". This "patch" consists of the retroperitoneal hematoma over the low-out site and the pressure developed on this hematoma by an intact retroperitoneal fascia, posterior and anterior abdominal wall musculature which balances against the decreased intra-aortic pressure. Pre-operative re-perfusion to near physiologic levels will result in destruction of this fragile equilibrium resulting in intra-peritoneal cavity hemorrhage. Due to the insistence on underhydration, the aorta remains flaccid (facilitating its surgical dissection; see section 5) and minimal to no intra-peritoneal hemorrhage was encountered in all cases.
- 3. An intra-operative blood recovery machine (cell saver) is used to decrease the amount of transfused blood components. Perioperative blood replacement in the specialized SSHP cases was 5 units of blood bank Packed Red Cells (PRC) and 5 units of cell saver PRCs with average operative blood replacement of 10 units PRCs.
- 4. All measures were employed to avoid hypothermia as it has severe adverse effects on coagulability, cardiac function, and

Table 2: The SSHP patients' demographics were compared with an "indirect historic control".

THISTOTIC COLLEGE .		
CONDITION	% of CR PATIENTS with CONDITION	% of SSHP PATIENTS with CONDITION
COLLAPSE	30%	7%
SYNCOPE	14%	73%
HYPOTENSION <100 mmHg	45%	87%
RESPIRATORY ARREST		13%
CARDIAC ARREST	8%	7%
PRE-OP MYOCARDIAL	22%	27%
INFARCTION		
CORONARY ARTERY DIS.	31%	33%
CAROTID ARTERY DIS.	6%	27%
HYPERTENSION	30%	40%
PERIPHERAL VASCULAR	16%	27%
DIS.		
RENALDIS.	5%	7%
C.O.P.D.	15%	20%
ARRYTIIMIAS	15%	20%
>80 YEARS OLD	15%	27%
MALE	78%	73%
FEMALE	22%	27%
BLACK	6%	7%
HISPANIC		13%
MORTALITY	48%	7%
SMOKING HISTORY		60%
ANTI-COAGULATION/ COUMADIN		33%

re-perfusion. This is very hard if not impossible to reverse in a small community hospital setting. Prevention can be difficult but is facilitated by: warming the operating room to 75 to 80 degrees; placing warming blankets (Bair Hugger/Arizant) on the extremities, chest and head; hot saline irrigation of the peritoneal cavity and its contents; and warming to physiologic temperatures of intravenous fluids, banked blood and blood products, cell saver blood, and medications.

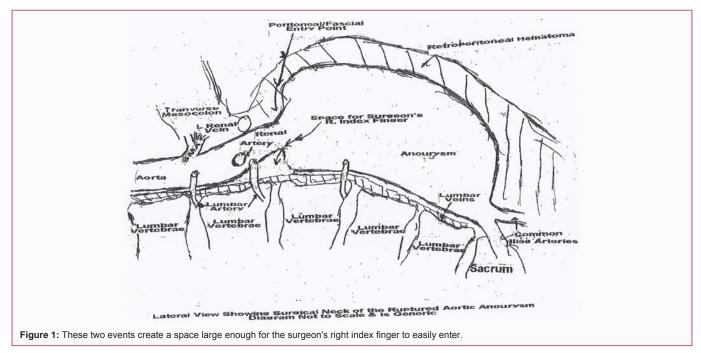
This is the essence of the SSHP. The abdomen is opened 5. with a standard midline abdominal incision from xiphoid to pubic symphysis and the bowel is eviscerated very rapidly, which may cause tears of the bowel if adhesions are present. Clamp the tears in the bowel and keep moving. Next, the retroperitoneum over the proximal dome of the aneurysm is opened without regard to intraperitoneal blood or bleeding from the hematoma there is no direct visualization after this point. The surgeon's hand follows the proximal dome of the aneurysm to the lumbar vertebrae and the thready pulse on top of it This is the surgical neck of the aneurysm and it is bluntly dissected free of the left sided retroperitoneal structures including inferior mesenteric vein. The surgical neck has been elevated from the lumbar vertebrae by growth of the posterior portion of the aneurysm. The lumbar arteries and veins are elongated by the growth of the posterior body of the aneurysm. The hypotensive aorta (section 3) is flaccid. These two events create a space large enough for the surgeon's right index finger to easily enter (Figure 1). The lumbar arteries and veins will feel like tight sutures. The aorta is manually clamped between the

Table 3: Morbidity.

· auto of more and .			
Acute Transient Renal Failure NO Dialysis	7%		
Acute Tubular Necrosis - Short Term Dialysis			
latrogenic Sigmoid Colon Trauma	7%		
Prolonged Assisted Ventilation	27%		
Deep Venous Thrombosis	7%		
Diverting Ileostomy for Massive Fecal Concretions /Diverticulosis Sigmoid Colon	7%		
Surgical Evacuation Abdominal Wall Hematoma	7%		
Thoracotomy for Evacuation of Thoracic Mediastinal Hematoma 2nd to heparin	7		

thumb and index finger in the first three to four minutes of opening the abdomen. No evidence of the aneurismal wall tear was found to be extending into the surgical neck of any of the 15 aneurysms. While the anesthesiologist is stabilizing the patient, dissection of the flaccid aorta from the inferior vena cava is accomplished. Arterial lines and central venous Swan-Ganz catheter lines are inserted during stabilization by the anesthesiologist. Stabilization includes full volume replacement to physiologic blood pressure, control of acid base balance, and restoration of urine output. Digital control is then switched to clamp control of the surgical neck. The iliac artery system back-bleeding is initially controlled either by manual compression of the distal aorta and iliac systems and or Fogarty/ Foley catheter insertion by the assistant surgeon until the mechanical cross clamp of the aortic neck of the aneurysm is completed. Fogarty catheter insertion into the iliac arteries is completed or direct clamping of the iliac arteries/ distal aorta is then done. Of all the cross clamp locations including intra-thoracic, supra-renal and endovascular balloon occlusion. Cross clamping at the surgical neck of the ruptured aneurysm decreases visceral and renal blood flow the least and therefore tends to be the least physiologically disruptive of organ function. This diminishes the amount of Liver/renal/visceral ischemia and necrosis with subsequent lactic acidosis, release of cardiac toxins and toxin interference with the clotting cascade. Laceration of a section of small bowel with spillage from the laceration occurred in one patient upon taking down adhesions on entry. This was clamped and after the ruptured aneurysm was repaired, the bowel was repaired. With >12 month follow up no graft infection occurred. Division of the left renal vein with repair at the end of the case and implantation of the inferior mesenteric artery can be used if needed, but these options were not utilized in this series.

- 6. The use of less than 2000 units of heparin for the whole case including monitoring lines and cell saver is the ideal. This dose created no bleeding problems in 12 patients. Missing this ideal goal; and giving >3500 units led to fortunately reversible difficulties in 3 patients. No attempt was made to reverse chronic pre -operative Coumadin. NO Systemic Heparinization was given.
- 7. Tube and bifurcated woven Dacron grafts were used. If common iliac artery aneurysms are present or if the aortic bifurcation is un-repairable, it is excluded and a bifurcated graft is used.
- 8. Do only enough surgery to get the patient out of the operating room alive. A Fogarty catheter is used to retrieve clots and debris from the iliac and proximal femoral artery systems. New clots are formed in the graft and aorta. They are expected and removed using suction attached to the cell saver. If proximal lower extremities are remotely viable, no other repair should be attempted.
  - 9. Post-operative care should mimic that given to "sick" post-



operative open-heart surgery patients including vigorous rhythm control, cardioversion, diuretics, and volume replacement.

This replacement in order of preference is: packed red blood cells, fresh frozen plasma, platelet packs, cryoprecipitate, Hespan & crystalloids.

#### **Results**

Fifteen of 15 patients survived for 21 days for a 0% mortality. Fourteen of the 15 SSHP patients survived >45 days for a mortality of 6.7%. No intra- operative mortality occurred. Surgery averaged 199 min (70 to 365): Aortic clamp time averaged 109 min (45 to 170).

# Mortality

The only post-operative mortality occurred in a 77 years female who has muscular dystrophy. Due to this muscular dysfunction of her chest wall she could not cough effectively. This obese patient had a pre-operative pneumonia and multiple 90% LAD coronary artery stenoses. Greater than 3500 units of heparin were given during a successful surgery. A post-operative abdominal wall hematoma requiring surgical evacuation occurred followed by a peri-operative myocardial infarction. On her 14<sup>th</sup> post-operative day, she developed a right lower lobe abscess, septicemia, multi-organ failure, and Acute renal Tubular Necrosis (ATN) requiring dialysis. She expired after 21 days.

#### Morbidity

Fourteen % had ATN that required up to 2 dialysis runs for resolution. Fourteen % had pre-operative chronic renal failure with creatinine of 1.6 & 2.2 progressing to 9.0 & 2.8 prior to returning to 1.3 & 2.1 at discharge all other complications are listed in Table 3 and were successfully treated.

# **Discussion**

CR group surgeons tended to employ 3 to 5 of the SSHP concepts. They either do not use surgical neck cross-clamp or if they do, they do not use it as much as is done in the SSHP protocol. Where enough CR report surgical technique details are available [2,3,5,7,28,30,39],

the mortality is 47% with 1,095 deaths/2,890 patients. There is a statistically significant difference in mortality (p<0.001; two tailed test) when compared to the mortality of the SSHP.

A statistic's probability of being correct or true is delineated from standard mathematical equations and tables that produce a number (0.1 to 0.0001). The smaller the number, the closer to "true" the statistic is and the more likely the results are to be repeatable. In other words, even though there are only 15 SSHP patients in this study, if the study were continued, 14 consecutive deaths would be required for the mortality of this technique to be 50% (CR) or 3 deaths in the next 4 patients for 25% mortality. Much attention has been paid in some research papers [1,2,5,16, 17,21,22,27,41] to determining which patients with ruptured abdominal aortic aneurysms to treat because of the waste of scarce resources on the 30% to 70% of patients unlikely to survive. Hospital costs, lack of adequate reimbursement, depletion of blood bank stores, and remaining quality of life are often cited in this discussion. The SSHP takes all patients without trying to determine who will live or die. The remaining quality of life after 45 days for SSHP patients is about the same as for a coronary artery bypass patient [13,41-47]. SSHP patients went on to resume their life styles with the expected gradual downward spirals from associated disease processes. In view of the low mortality of the SSHP, the expenses and reimbursements for these patients should be the same as for moderately "sick" coronary artery bypass patients. The retroperitoneal hematoma contains 1 liter to 3 liters of clotted blood and there will be several hundred CC.S of blood in the peritoneal cavity, drapes, sponges, and "cell saver". All of the blood in these areas represents lost clotting factors. One third of the patients in SSHP were clinically anti-coagulated with Coumadin (1 with an INR of 3.5) and this is not reversible. The use of <3000 units of heparin total from "cell saver", and monitoring line heparin, does not seem to disturb the ability of the remaining clotting system to make clots. The surgeon must be ready to suction new clots from the lumens of tube and bifurcated grafts and use Fogarty catheters and back-bleeding of the iliac system to clear clots without feeling pressure to fully anticoagulate the patient. The reward is as follows: these patients do not

bleed out through their incisions and graft walls in the operating room or the ICU; the operation takes much less time; and the post-operative course is much smoother. The basic aim of the SSHP is to save the patient's life. Doing additional revascularization, while convenient at the time of the initial surgery, uses up clotting factors, requires more heparin, exposes the patient to more anesthesia, increases hypothermia, increases acidosis, increases cardiotoxins, and increases post-operative metabolic! Cardiac requirements. Additional vascular repairs can be done as needed in the mid to late post-operative period. The equipment used in the SSHP can be found in any hospital capable of rudimentary vascular surgery/orthopedic surgery in this country or elsewhere in the world. All the SSHP requires is a change in the thinking processes of the surgeon and in surgical training. The SSHP needs an expanded clinical trial to determine if other surgical groups can match or, as I suspect, improve on these results. If this can be accomplished, the dismal outlook for patients with ruptured abdominal aortic aneurysms would be improved, especially in areas where more limited medical facilities are available.

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