The Sternum Support Harness for the Treatment of Sternotomy Pain and the Prevention of Sternal Instability

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Most open heart procedures are performed through a median sternotomy, in which the manubrium and the entire sternum are divided centrally, and separated widely with retractors to allow access to the great vessels and the heart.[1-3] Following surgery, the sternum is closed with stainless steel wires.[3] In the large majority, the sternotomy heals with no major complications; however infection, mediastinitis, and dehiscence of the wound do occur in a significant number of cases. The incidence is variously reported to be from 1% to 5%, [4-7] with mortality rates in the last 10 years of 15% to 40%. [8-12]

To prevent dehiscence and to reduce pain postoperatively, patients are instructed by physical therapy (PT) and other staff to stabilize the sternotomy with a pillow, especially while coughing.[13,14] Hospitals issue heart-shaped pillows and teddy bears for the purpose, but this splints the wound in one plane only, and does not offer circumferential resistance to increased intrathoracic pressure during forceful activity. One case of unusual sternal non-union, brought to our attention a year after surgery, led the physical therapy team on our cardiac rehabilitation unit to investigate more effective mechanical means to stabilize the thoracic cage. The principle method employed was a relatively inexpensive sternum support harness (Figure 1, General Cardiac Technology, Inc., Santa Cruz, CA) which was used by patients with complaints of sternal pain, or with signs of wound dehiscence or instability.

The importance of preventing dehiscence of the sternotomy is underlined by the severity of possible complications and the costs of repair. The integrity of the incision is disrupted by sternal instability, which may allow bacteria to spread into the mediastinum.[9,12,15,16] Inflammation or ischemia of the disrupted incision, and necrotic bone fragments, can further promote the development of infection which might involve any of the mediastinal organs, prosthetic valves, and surrounding structures.[11,17,18] A common source of bacteremia after coronary artery bypass graft (CABG) is the sternal wound.[19] Mortality rates are high, and there may be long-term effects of osteomyelitis, endocarditis, and sternal instability or complete non-union in survivors.[7,12,15,20-22] Upon re-exploration, the usual finding is that the wires have pulled through the bone, rather than breaking or coming undone.[16] Some patients can be successfully treated with sternal debridement and rewiring.[17,23] The sternum must be widely debrided; incomplete removal of necrotic tissue is implicated in treatment failure.[17,23] Even when the wound is sterile, rewiring is often followed by major infection.[9,17] If the closure fails again, further debridement is required, which precludes rewiring, since a significant portion of the sternum is removed.[17] The wound is reconstructed with vascularized muscle flap procedures using pectoralis or rectus, sometimes in conjunction with omentum.[4,24] Some surgeons report stable chest wall configuration on follow up,[4,18] but long-term studies at an average of about 4 years later found that 42% to 45% of patients complained of sternal instability.[7,24] While it is not always clear whether instability is the cause or the result of infection, the two are strongly associated with each other,[8,25] and every effort should be made to prevent either. The increased length of stay and the additional operations can multiply the hospital charges up to 4 times that of an uncomplicated CABG.[12,26,27]

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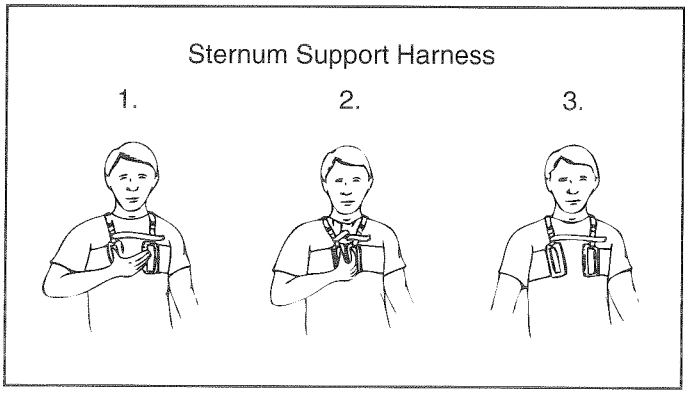

Figure 1. Sternum Support Harness. Used with permission from General Cardiac Technology, 15814 Winchester Blvd., #105 Los Gatos, CA 95032

RISK FACTORS

Major risk factors for sternotomy complications have been identified and discussed extensively in the literature. Since studies use various methods and consider different variables, the results do not always coincide, but those listed below are frequently cited and there is clear evidence to support them. The preoperative conditions of chronic obstructive pulmonary disease (COPD), diabetes, obesity, malnutrition, osteoporosis, and hospitalization can all be indicative of underlying disease, poor condition, and depressed immune function.[9,12] A prolonged hospital stay, either before or after surgery, exposes the patient to hospital flora which can put him at greater risk of infection.[8,12] Increased age may not be a risk factor in itself, but significant diseases such as diabetes and COPD progress with age.[9]

Since the internal mammary arteries (IMA) provide the principle circulation to the sternum, using them as conduits for CABG reduces blood supply to the wound, especially when they are harvested bilaterally (BIMA).[5,28] Small vessel disease associated with diabetes also causes deficits in wound perfusion.[12,21] In one study, diabetes and the use of BIMA in combination were found to be independently significant predictors of sternal wound complications.[10] Prolonged time for surgery, bypass, and aortic cross clamp allow a longer exposure to contamination of the large chest incision, to ischemia from instrumentation, and to the temporary vasoconstriction, hypovolemia, and immunosuppression associated with coronary bypass.[11,12,21] Significant bleeding can lead to hematoma formation in the dead spaces of the mediastum, providing an ideal environment for the growth of bacteria.[11] It also can reduce blood volume, increasing the need for exogenous blood transfusion, which has been shown to reduce immunological competence.[11,12] Inotropic support required postoperatively is indicative of low cardiac output, causing hypotension with diminished perfusion pressure to the wound. In addition, inotropic agents direct circulation toward vital organs, decreasing the supply to peripheral structures such as the sternum and skin.[9,12,21] Postoperative respiratory problems and ventilator support, especially with tracheostomy, are usually associated with underlying COPD, and can lead to direct contamination of the sternotomy from sputum. Nasopharyngeal organisms have been correlated with cultures from the infected mediastinum.[8,10,12]

A special feature of the median sternotomy is that it is subjected to the constant motion of breathing.[5] The major risk factors of obesity and COPD can add to this mechanical stress on the wound. In an obese patient, added body weight leads to increased lateral tension, tending to pull the sternal halves apart.[8] In patients with COPD, the intrathoracic pressure is likely to be raised by the need for prolonged ventilator support with positive end expiratory pressures, as well as by the excessive coughing associated with respiratory problems.[2,8,20] In one study, the use of ß-adrenergic drugs, which the authors regarded as a sign of COPD, increased the risk of postoperative mediastinitis 20-fold; obesity doubled it.[8] Sternal instability was associated with only these 2 risk factors, and not with any others. This seems to implicate instability as the cause of infection leading to mediastinitis in these particular cases.[8] Excessive strain on the sternal wiring may cause a higher risk of dehiscence, which can allow bacteria to spread inward from the cutaneous regions, leading to mediastinitis.[8,9,15,16]

CASE HISTORY

The following history illustrates a case in which a man with identifiable risk factors may have benefited from a sternal support harness to prevent dehiscence of his wound following bypass surgery, and to avoid the long-term effects of sternal nonunion.

A 63-year-old man (Mr. H) with a history of angina for about 1 month, described as left arm numbness, jaw pain, diaphoresis and dyspnea on exertion, was determined on cardiac catheterization to have severe coronary artery disease. Prior to the onset of angina, he was an active man, retired from a 32-year army career, and employed as a school bus driver. He had a history of chronic, sustained, and forceful cough of unclear etiology which had been studied extensively and treated by the Lahey Clinic and by Walter Reed Hospital, with no definitive resolution. He carried a diagnosis of chronic obstructive pulmonary disease, with an insignificant smoking history. There was a related family history; his mother, who had never been a smoker, had a similar chronic cough.

Table 1 Major Risk Factors

Preoperative conditions
- Chronic obstructive pulmonary disease[2,5,8,9,15]
- Increased weight, obesity, or body mass index (BMI) more than 25[1,5,8,10,15,20]
- Diabetes mellitus[5,10,15,25]
- Preoperative hospital stay[8,11]
- Age[1,9,12,21]
- Osteoporosis[5,20,21]
- Malnutrition[5,12]

Operative factors
- Bilateral internal mammary artery harvest[5,10,18,25,28]
- Increased time for surgery > 3 to 4.5 hours[2,8,11]
  - for bypass > 1 hour 25 min.[2,8]
  - for aortic cross-clamp >.8 hours[8]
- Units of transfused blood[10,11]
- Blood loss[10,11,20]

Postoperative factors
- Increased ICU stay > 2 to 3 days[2,9,11]
- Inotropic support[9,12,20]
- Ventilator support > 12 to 48 hours[1,2,8,10,20]
- Respiratory complications or failure[9,10,12]

Mr. H was admitted on 10/28/96 to a tertiary medical center for triple bypass surgery, via median sternotomy, with LIMA and sequential saphenous vein grafts. The sternotomy was closed with #6 stainless steel wires. The bypass time was 1 hour and 9 minutes, the cross-clamp time was 50 minutes, and no exogenous blood was used. After brief temporary pacing, the heart regained spontaneous normal sinus rhythm. He was extubated in the intensive care unit on postoperative day 1, and was seen at that time by physical therapy for postural drainage, percussion and vibration, splinted coughing, and bed mobility. He was transferred to a regular floor on day 2, was seen for continuing chest PT and progressive ambulation and stairs, with no unusual problems. His wounds were healing well, he was afebrile, and there was no evidence of sternal infection. He was discharged on 11/5 (PO day 8) with a home walking program, and a teddy bear for splinted coughing.

His wife reported that his usual uncontrollable cough did not return in full force until his second day home, about 10 days after his surgery. He attempted to splint himself as instructed with the teddy bear, but felt the wound tear, and found himself bleeding copiously. He was directed to staunch the flow with towels; this worked for a few hours, but when the drainage increased he went to his local emergency room, and was referred back to the medical center, 70 miles away. He had a clear sternal dehiscence, with a click in the mid to lower third, and expressible serosanguinous drainage. He was coughing, and had decreased breath sounds at the bases. Cultures from his wound were negative, and he was afebrile. He was treated with broad spectrum antibiotics and was closely observed by infectious disease and cardiology consultants. After a 10-day stay, there were no signs of sternal wound infection, and the decision was made to treat him conservatively with oral antibiotics. He was discharged home with instructions to stay in close contact with his cardiac surgeon.

He remained at home for about 2 weeks without signs of gross infection. The discharge from the wound did not become purulent, but it increased in quantity, and the wound did not heal. His wife, who changed his dressings, noted an opening with an air leak and surrounding redness. He was readmitted for nonhealing sternal wound dehiscence, with plans for muscle flap procedure. There was a central opening of about 1 cm, with surrounding erythema of 2 cm, the sternal halves rocked against each other and culturettes could be passed easily through the dehisced halves. In the operating room, all sternal wires were found to be completely pulled through the sternum, and there was a large amount of granulation tissue along the medial border, consistent with sternal dehiscence for some time. The wires were removed, and the bone was debrided back to healthy bleeding tissue, several millimeters on each side. Bilateral pectoralis major myocutaneous advancement flaps, extending deep to the rectus sheath, were used to close the chest wall. The sternum was not rewired. Since the patient had been on an aspirin a day up to the day before surgery, there was a fair amount of oozing throughout. He did not receive any exogenous blood during or after surgery, and he was extubated in the operating room. Mediastinal fluid, portions of subcutaneous tissue, and portions of bone were sent for aerobic and anaerobic culture. There was no growth, and no organism seen, and he was put on prophylactic antibiotics.

Postoperatively he reported incisional tightness, and was febrile and lethargic, but this gradually resolved. Aggressive pulmonary toilet and early ambulation were ordered and he was seen by PT for postural drainage, percussion and vibration, deep breathing exercises with manual cues to increase lower chest wall excursion, and for walking. The pulmonologist was consulted for cough suppression and prescribed inhalers. After a 10-day course of IV antibiotics and close observation for any signs of infection, he was discharged with 1 drain still in place. All of his cultures continued to be negative. He returned as an outpatient for removal of the drain, which had become clogged, and several times for needle aspiration of serosanguinous fluid from a large central seroma that formed across his chest. This final complication was resolved after a few weeks, the suture line healed with no further problems, and he did not return to his surgeons. His chronic cough did not disappear, and he attempted to splint himself with his hands, which he felt were more effective than a pillow. He was not referred to an outpatient cardiac rehabilitation, but he did do some mall walking, in compliance with a home walking program. He was not allowed to return to work for 2 months, and his wife felt that there were some signs of depression during this period.

Mr. H was followed after discharge by his local cardiologist. He began to develop painful muscle spasms in his posterior chest wall, and his sternum remained markedly unstable, but this was expected to become solid over time, and he was not treated for it. About 10 months after his CABG, during a brief hospitalization for a broken jaw, he was noted to have a dramatically unstable sternum, and was advised to return to his original surgeons. When he coughed, there was an excursion of his clavicular heads of about 3.5 inches, and of the sternal halves at the level of the xyphoid of about 1.5 inches. When he was not coughing, his clavicular heads were juxtaposed. Furthermore, in a side lying position, the 2 sternal halves overlapped each other, and when he rolled over in bed, they tended to grind against each other, which also happened during physical activity.

After waiting for his jaw to heal, he did discuss the problem with his cardiothoracic surgeons, who arranged for him to see his plastic surgeon as well, on the same day. The possibility of further surgery was discussed, the disadvantages being primarily that since his sternum had already been debrided, and would have to be debrided again, the circumference of his chest would decrease and he would probably experience a feeling of tightness and compression. Also, since his bone had already proved to respond poorly to hardware, and he still had his cough, chances of good closure were poor. The surgeon was able to assure him that his heart was well protected by fibrous tissue, and most importantly, he was happy to give him a letter stating that he could safely return to work as a busdriver. After this discussion, he decided that he did not want to undergo any more surgery, and would therefore, in his words, "live with it."

At the present time, 3 years after his CABG, his sternal instability persists, and he continues to have painful muscle spasms which limit the vigorous activity that he used to do. The abnormal motion of his chest wall, and the sensation of grinding disturb his sleep. He always feels tired, but he continues to work as a bus driver, enjoys his family, and tries to remain active.

CLINICAL TRIAL

To treat the pain associated with sternotomy wounds, and possibly to control dehiscence, we employed a sternal support harness in a clinical trial in our cardiac unit at Helen Hayes Hospital, which is a rehabilitation facility. The harness consists of a broad belt, 4 inches wide, with suspenders from the shoulders to keep it in place. The belt is finished with a handle on each end, adjusted to be a hand's width apart at the center of the patient's chest. During activity or while coughing, the patient grips the handles, which tightens the belt encircling his chest, and splints the sternal wound by stabilizing the thoracic cage. At rest, it remains loose, and does not restrict normal motion during breathing (see Figure 1).

The harness was used by 14 patients after open heart procedures via median sternotomy; 11 of them had undergone CABG, 3 of them had valve replacements. They were admitted an average of 1 week after surgery, from 3/98 to 10/98. They presented with complaints of severe sternal pain limiting participation in therapy, debilitating pain preventing participation, or with signs of wound instability, defined as movement or click of the sternum palpable by the clinician. Instability was noted in only 2 patients. The most common risk factor in this group was a high body mass index (BMI); all of the patients had a BMI of more than 25 (overweight), and 12 out of the 14 had a BMI of more than 30 (obese). Ten of the patients had a history of respiratory conditions, the left IMA was harvested in 7, including one whose right IMA had been harvested earlier, and 5 had diabetes. There were 8 females and 6 males in the group.

The harness was demonstrated, its use was explained, and it was adjusted to the size of each patient, who was then instructed on how to use it. The patients were asked to assess their pain on a scale of 0 to 10, before and after using the harness, and to report any other subjective findings. It was emphasized that they should use the device only if they

found it helpful; they were not required to use it.

Two of the 14 patients had cognitive deficits, and could not express their pain in terms of numbers, although they both indicated that they wanted to keep using the harness. One of these 2 had rheumatoid arthritis, and it appeared that his hands were too arthritic to use it effectively. Of the remaining 12, 9 patients (75%) reported a mean reduction in pain of 4.4 points, and reported that it was especially helpful while coughing. Two patients found the harness to be awkward, and did not use it. One tried it for a day and said that her pain did not change much. Neither of the 2 patients with a palpable sternal click showed any reduction in instability. Most of the patients used the device for about a week; as their general condition improved, their pain diminished. Only one patient received the harness in the acute care hospital, 2 days after his surgery, and continued to use it for about 3 weeks. This patient had 4 major risk factors; he was diabetic, obese, he had COPD, and

Table 2. Patient Characteristics

Pt.#	Adm. Date	Diagnosis	Sex	Age	IMA[1]	BMI[2]	Diabetes	Respiratory problems
1.	3/09	CABG[3] Stable sternum, debilitating pain	M	74	LIMA[4]	43		COPD[5], post op. respiratory distress
2.	4/01	CABG Stable sternum, severe pain	F	82		26		
3.	4/07	CABG Stable sternum, debilitating pain	F	52		36		Persistent cough
4.	4/08	MVR[6] Stable sternum with small amount of drainage, debilitating pain	F	50	LIMA	31		
5.	4/21	CABG Stable sternum, severe	M	70		34		Asbestos exposure
6.	4/28	CABG Sternal wound infection, partial dehiscence, debilitating pain	F	72	LIMA	33	IDDM[7]	
7.	7/20	CABG, PVD[8] Sternum unstable, (+) click	M	71	LIMA	33	IDDM	COPD
8.	7/31	MVR	F	40		36		Asthma
9.	8/30	CABG Stable sternum, severe pain	F	82	LIMA	30	IDDM	COPD
10.	9/21	AVR[9] Stable sternum, severe pain	F	66		46		Asthma
11.	9/28	CABG Stable sternum, debilitating pain	M	49	BIMA[10]	33	IDDM	COPD
12.	10/09	AVR Partial sternotomy, debilitating pain	M	70		32		Firefighter, retired
13.	10/09	CABG, RA[11] Sternum unstable, (+) click	M	70		33	NIDDM[12]	Pneumonia
		Stable sternum, severe pain	F	76	LIMA	28		

1. IMA: Internal mammary artery
2. BMI: Body mass index; >25:overweight,>30:obese
3. CABG: Coronary artery bypass graft
4. LIMA: Left internal mammary artery
5. COPD: Chronic obstructive pulmonary disease
6. MVR: Mitral valve replacement
7. IDDM: Insulin dependent diabetes
8. PVD: Peripheral vascular disease
9. AVR: Aortic valve replacement
10. BIMA: Bilateral mammary arteries
11. RA: Rheumatoid arthritis
12. NIDDM: Non-insulin dependent diabetes

Table 3. Results

Patient #		Pain level without harness-with harness
1.	The patient reported that the harness centralized the pain around the sternum, and stopped it from radiating. It did not make it disappear. He wore it all hours.	8/10–4/10
2.	The patient thought the device was awkward, and shortly returned it.	
3.	The patient said that she needed the harness badly as long as her cough persisted. She wore it for four days; when the cough was gone, she no longer used it.	8/10–4/10
4.	The patient returned the harness the next day, and said she did not like it.	
5.	The patient remarked that by the time he started looking for a pillow at midnight, it was too late. He said the harness was more available when he had to cough, and relieved pain much better.	8/10–4/10
6.	The patient was unable to express her pain levels in terms of numbers. She said the harness was helpful and wanted to keep it, but was seen to wear it only occasionally.	
7.	The patient reported that the device was better for pain relief because it went all the way around the chest and seemed to hold him together, especially while coughing.	8/10–4/10
8.	The patient said she thought her large breast size made her pain worse than it might have been; the pain was much better with the harness.	9/10–3/10
9.	The patient reported that the harness did not help much.	
10.	The patient said that the harness helped quite a bit with the pain. She wore it throughout the day, and said it was more available, since she was wearing it.	9/10–3/10
11.	The patient stated that his pain before using the device was beyond maximal: *15110*. It was important immediately after surgery, especially with coughing. He used it for three weeks.	10/10–6/10
12.	The patient reported that without the harness, he could hardly move. He preferred it to a pillow because it went all the way around.	9/10–3/10
13.	The patient said he liked the device, but could not express his pain level in terms of numbers. His hands appeared to be too arthritic to make effective use of it.	
14.	The patient reported that the harness helped with pain when she coughed, and that she did not have to carry a pillow around with her.	7/10–3/10

BIMA had been used (the RIMA for a prior procedure). He said that the device was important immediately after surgery. He insisted that his pain before he received it, using a pillow to splint himself, was beyond maximal: 15/10. However, we used the assigned maximal value of 10/10.

This limited trial seems to indicate that the support harness may be useful for pain management, but a larger sampling would be needed to verify this. To assess its usefulness as a preventative tool, a larger study could also be done immediately postoperatively in the acute care hospital especially with patients identified as being at risk for complications.

DISCUSSION

Deep breathing and splinted coughing are important PT interventions after surgery because ciliary clearance of secretions is impaired, mucous is thicker, and there is atelectasis of the distal airways as a result of anesthesia.[13,30] The ability to cough effectively is severely limited by pain,[30] and coughing may sometimes threaten the integrity of the sternotomy.[17,31] Splinting the wound with a pillow or sometimes with the hands, to stabilize the incision and to control pain, is part of PT patient education.[13,14] It is reasonable to think that supporting the entire circumference of the chest wall with a harness will offer better resistance to raised intrathoracic pressures that sometimes tend to spread the sternum apart with such force that the wires pull through the bone. Our experience seems to suggest that this support may help to control the pain associated with the incision, thereby promoting compliance with deep breathing and coughing. Since the patient can wear the harness it has the advantage of being available when the need arises, for instance, during therapy, or when the patient wakes up at night. We can only speculate that it might preserve sternal

stability; complications arise before patients arrive at our rehabilitation facility and receive the harness. We might infer, however, that the forces that cause pain are also the forces that cause dehiscence, and that effective mechanical treatment for one would be effective for both.

Studies of sternal wounds describe major complications as those that require reoperation.[8,15,25] Serious problems that fall short of needing surgical intervention may go unreported. Complications arising after hospital discharge also may not be included in these studies.[2] Patients often see their local physician rather than returning to the large medical centers where open heart surgery is performed. It would be interesting to see a long-term study, tracking dehiscence of the sternal wound regardless of whether reoperation is required, comparing traditional splinting methods with the use of a sternum support harness immediately after surgery.

More health care resources are spent on coronary artery bypass graft surgery than on any other single procedure, and sternal wound complications are the clinical variable most likely to escalate hospital costs.[26,27] With 360,000 operations performed annually in this country for CABG,[31] at a conservative estimate of 3%, sternal wound complications occur in about 10,000 of these patients a year. Median sternotomy is also performed for many other procedures, such as lung reduction, which can add to this figure. Cost effective measures, targeted at specific risk factors for median sternotomy dehiscence, can reduce hospital charges significantly.

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