Five-Year Follow-Up Study of Iliofemoral Venous Thrombectomy

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ILIOFEMORAL thrombectomy for acute deep vein thrombosis was described by Leriche in 1948 [5] and became known in America through Mahorner *et al.* in 1957.[6] Since then the operation has been variably accepted by American surgeons, and a series of 45 cases was reported from the University of Louisville in 1963 by Haller and Abrams.[2] The advantages of the operative procedure over elevation and heparin therapy were stated to be immediate relief of compromised venous drainage of the lower extremity, lessened morbidity, venous valve preservation, and prevention of the postphlebitic syndrome. Since all of the original Louisville group were operated on at least 5 years ago, an assessment of their status evaluates the validity of these assumptions.

Method

The operative technic has been previously described.[2] Hospital and clinical records of 39 of the original 45 patients were still available. Special attention was directed to the 34 patients who underwent operation less than 10 days after the onset of symptoms, since most investigators have agreed that this type of patient most likely benefits from the procedure. Hospital records determined the volume of blood transfused, incidence of wound infection and pulmonary embolus, mortality rate, and duration of hospital stay in the survivors. Seventeen of the 28 patients who were still alive were personally interviewed to assess the degree of edema, skin discoloration, ulceration and continued use of elastic support 5 years after operation. When the patient consented, a venogram of the operated and non-operated leg determined the presence of valves and competency of the deep venous system. The venograms were performed with the patient supine and the head elevated 5 degrees. Sixty cc. of 60 per cent meglumine iothalamate * were injected into an ankle vein with an occlusive tourniquet at midcalf or just below the knee, and films of the popliteal and femoral region were taken 90 and 180 seconds later.

Results

The records of six of the original 45 patients were lost or unavailable, leaving 39 patients for assessment of the immediate hospital morbidity and mortality rates: the results are recorded in Table 1. Ten patients died, five while still in the hospital. Three of the hospital deaths resulted from other diseases (heart disease, cancer and stroke) and two from pulmonary embolism that occurred 1 and 2 days after operation. The other five patients died later of other diseases or from unknown causes. Thus,

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two deaths were directly attributable to the operation (5%).

Of the patients who left the hospital, average duration of stay following operation was 30 days, ranging from 6 to 240 days. The median hospital stay of 12 days, however, gives a more accurate picture, since the average is distorted by one chronic disease patient who stayed 240 days. Blood transfusion was required in all but three patients, ranging from 100 cc. in a 13-pound child to 3,500 cc., with an average of 1,000 cc. Local wound infection or hematoma that had to be drained occurred in 12 of the 39 patients (30%), and non-fatal pulmonary embolus in one.

Early operative intervention (clinical disease present 1 week or less) was carried out in 34 patients, nine of whom died, and later operation in five patients, with one death. Only 17 of the 25 survivors of early operation could be interviewed, the other eight patients having disappeared without a forwarding address (Table 2). With one exception, all of these patients still had significant edema and wore an elastic support 5 years after operation, and one had a stasis ulcer that first appeared 3 months after operation. The only patient free of edema was a 6-year-old boy who underwent thrombectomy when he was 1 year old for the treatment of an infected long saphenous phlebitis that resulted from an ankle cutdown and extended into the common femoral vein: the thrombus in the iliac and femoral veins was removed and the saphenous vein was interrupted.

Venograms were performed on 15 of the patients who underwent early operation (Table 3). The involved area of the deep venous system was found to be incompetent in all cases and there were no functioning valves. Representative venograms are illustrated in Figures 1–4. Figure 1 shows a normal right leg at 90 seconds with valves in the superficial femoral vein while on the operated left side the vein is patent, but has no valves. At 3 minutes (Fig. 2),

TABLE 1. *Morbidity and Mortality in 39 Patients*

	No.	%
Transfusion (100–3,500 cc.; m = 1,000)	36	92
Wound infection	12	30
Pulmonary embolus	3	7
Deaths	10	26
Pulmonary embolus	2	5
Other causes in hospital	3	8
Late deaths	5	13
Hospital Stay in 34 Immediate Survivors		
Range 6–240 days		
Mean 30 days		
Median 12 days		

the right femoral vein is empty except for a trace of contrast material in the valve pockets, whereas the left side remains filled. Figure 3 shows another case with a normal right leg at 90 seconds with valves present, while the left superficial femoral vein has recanalized, but has no valves. In this same leg, the saphenous vein with its functioning valves is acting as a collateral that has been filled from perforating veins in the calf. Finally, Figure 4 shows the

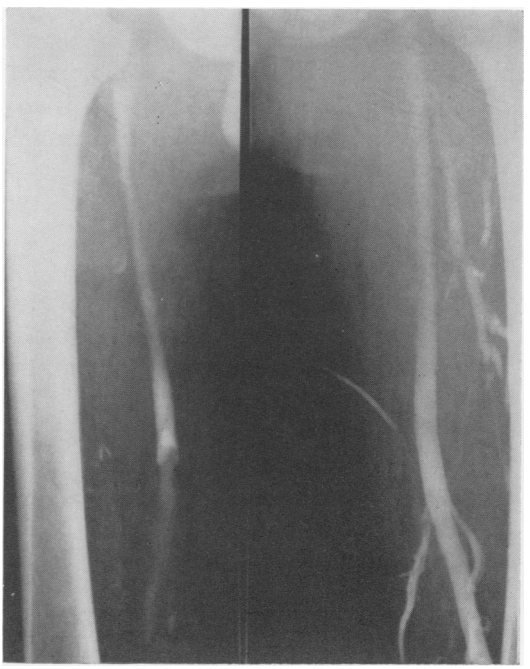

FIG. 1. Case 1. Normal right leg at 90 sec. showing femoral venous valves and no saphenous filling. Operated left side patent with no valves.

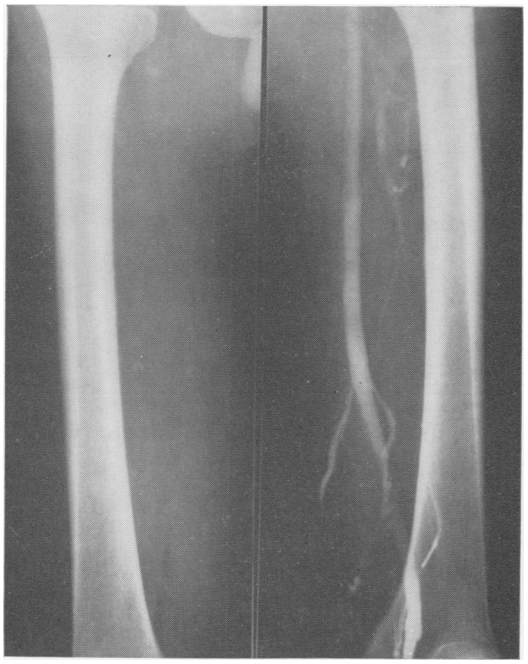

FIG. 2. Case 1. Right leg at 3 minutes. Vein empty except for a trace of contrast material in the valve pockets. Diseased left femoral vein still full at 3 minutes with absence of valves.

venogram in the child who was operated on at 10 months of age for saphenous phlebitis that extended into the iliofemoral system. The superficial femoral vein is still occluded and the collateral circulation is mainly through the deep femoral tributaries. Other films showed that the iliac veins were patent but diseased and the terminal vena cava was occluded, the venous return being by way of dilated lumbar channels on each side. Despite these marked changes in the venogram, the leg was clinically normal, presumably because the distal femoral and popliteal systems were not involved in the original disease and remained patent with functioning valves (Fig. 4).

Discussion

Previous reports of thrombectomy for the treatment of massive iliofemoral thrombosis have emphasized the immediate improvement in arterial and venous circulation, the decrease in swelling, and the patency of the veins in the early postoperative period. A long-term follow-up study of the results with repeat venograms to demonstrate patency and valve function has not been available until the present study. Unfortunately, this interpretation is complicated by the low percentage of follow-ups, caused by the transient nature of the indigent population that makes up the majority of the cases. Many of these patients had moved without any forwarding address and it was impossible to find them. However, the almost universal state of poor function that was observed in the patients that were rechecked is very suggestive of the picture of the overall group. If every one of the eight patients that could not be traced had a good result, which is very unlikely, the good results in the patients operated on in the first 10 days of the disease could only increase from 6 per cent (1/17) to 36 per cent (9/25).

The purpose of the operative procedure has been stated to be an immediate decrease in the morbidity of the patient, preservation of venous valve function, and prevention of the late effects of venous stasis in the legs. Evidently, these ideals were not met in the present group since the long-term results were not nearly up to the predicted levels. Although only one stasis ulcer had developed in this 5-year period, all but one of the patients had edema and wore supportive stockings. In none of them could functioning valves be demonstrated in the operative area by venography, and the contrast between the picture of the deep venous system in the operated and noninvolved leg was quite striking. The only good functional result was in the infant whose phlebitis started as an infection in a cutdown at the ankle and extended proximally in the saphenous vein to the common femoral vein. Because of severe ischemia and infection in the foot, a venogram was not performed in either the preoperative or immediate postoperative

TABLE 2. *Stasis Disease 5 Years After Early Operation*
(25 survivors of 34 patients)

	No.
Supportive stocking	16
Edema	16
Stasis ulcer	1
Normal	1*
Unknown	8

* Infant with distal veins not involved.

TABLE 3. *Valve Preservation 5 Years After Early Operation*
(25 survivors of 34 patients)

	No.
Venography	15
Deep venous insufficiency	15
Valves present	0
Refused venogram	2
Unknown	8

period. Perhaps the excellent result in this child represents the recuperative powers of a child, but more likely the distal femoral and popliteal veins were not thrombosed at the time of the operative procedure. This hypothesis is supported by the venogram 5 years later which showed normal veins and valves in the distal femoral and popliteal area, occlusion of the superficial femoral vein and distal inferior vena cava, and dilated collateral channels through the deep femoral system and the lower lumbar veins. Therefore, in the situation where thrombophlebitis extends from the superficial saphenous to the deep system, immediate removal of a recent occlusion of the deep venous system at the common femoral vein level may be effective therapy, particularly when the distal tree is still patent and has intact valves. However, further observation of cases of this type will be required to determine whether the operative result is superior to that of conservative therapy.

Along with the less than ideal functional result, the considerable morbidity and mortality of the operative procedure was also very impressive. Two deaths occurred from fatal pulmonary emboli in the first 2 postoperative days. It must be admitted, however, that most of the operative mortality was caused by the patients' original disease. Since the end results were only mediocre, patients should be more carefully selected for operation and a more conservative approach employed in the patient with some other critical illness. Aside from the mortality, the 30 per cent incidence of wound hematoma or infection, 7 per cent occurrence of clinical pulmonary embolism, and the average of 1,000 cc. of blood transfusion should provide reason to hesitate before undertaking a procedure in which the long-term results are questionable.

The immediate decrease in swelling with improvement of color and arterial inflow that follows the operative procedure has been attributed to the thrombectomy. However, each of the patients was treated with elevation of the leg and anticoagulation in the immediate postoperative period. We have frequently observed the same dramatic improvement without operation when the leg was elevated to 30 to 45 degrees and 10,000 to 15,000 units of heparin were given intravenously. The pain, numbness, cyanosis, and tissue tension have improved so much within 1 to 2 hours that a scheduled operative procedure has almost always been cancelled.

The importance of deep venous patency in the immediate postoperative period has been emphasized and established as an aim of the operative procedure. Use of the Fogarty catheter has been recommended as an aid to complete removal of clot from the distal veins.[3] However, the catheter must be passed in a retrograde fashion and hence damage to the venous valves is very probable. Consequently, another major purpose of the operation, that is, preservation of valve function and venous competency, will be defeated by this maneuver. Aside from this objection, patency of the

FIG. 3. Case 2. Right leg normal at 90 sec. with functioning valves. Operated left superficial femoral vein has thrombosed and recanalized. No valves are seen in it, but are present in the saphenous vein which is filling from incompetent distal perforating veins.

deep venous system does not by itself assure a good final result, as our series demonstrates so well.

Emphasis has also been placed upon early operation, that is, less than 10 days after the onset of the process, but in this series we could not see any difference in the end result between patients operated on early and those operated on after 10 days. It would be difficult to demonstrate any benefit, of course, since the results of early operation were less than ideal anyway, and there were only five patients operated on after 10 days, one of whom died of another cause.

Favorable results have, however, been reported by other authors,[2, 3, 4, 6] so we were concerned about the discrepancy between those reports and this series. Twenty-two of the 48 patients operated on by Kaiser *et al.*[4] were patients with saphenous phlebitis that resulted from a venous cut-down, and extended into the femoral vein, while only one of ours was of this type. It is interesting that this was our only good result, and the striking picture in the follow-up venogram has already been described. Mahorner *et al.*[6] also reported good results from the operation in 12 of 13 cases of acute iliofemoral thrombosis. Their selection of cases and operative methods were similar to those used in this series, but they employed continuous intravenous infusion of heparin into the involved leg for 3 or 4 days postoperatively, followed by intramuscular heparin for an unspecified period. This local heparin therapy may have accounted for some of their success.

While the type of case and some variation in technic may account for some of the discrepancy in results, the important difference between the present report and pre-

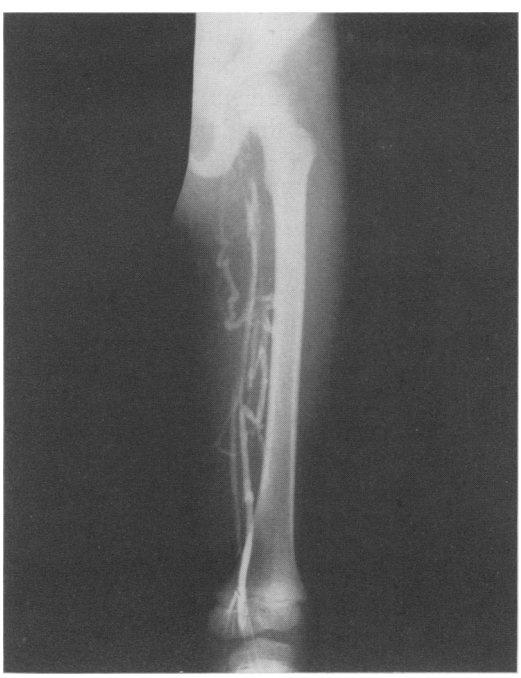

FIG. 4. Case 3. The 6-year-old child who had a good result from operation at age 10 months. Most of the superficial femoral vein is occluded and the deep femoral collaterals are dilated. Note the valves in the distal femoral and popliteal veins. Other films showed the recanalized iliac veins and occluded distal inferior vena cava with lumbar collaterals.

vious series is the length of follow-up study. Mahorner *et al.*[6] had a median follow-up period of 4 to 5 months and were careful to state that the long-term results were not yet known. Follow-up periods were not stated by Kaiser *et al.*,[4] and were only 3 days to 9 months in the cases reported by Harris and Brown.[3] The present series was previously reported by Haller and Abrams [2] with an average follow-up period of 18 months. At that time 26 of the 31 survivors operated on less than 10 days after the onset of symptoms were reported to have clinically normal limbs (84 per cent). It is evident that this pleasant state of affairs has not been maintained.

Why are the late results so poor? Certainly venous patency is not the factor, since 15 of 18 venograms performed early in this series were reported to be patent.[2] Unfortunately, they have been misplaced so that a search for functioning valves in the venograms done at that time could not be made. Edwards and Edwards [1] reviewed the pathological processes involved in recovery of veins after thrombosis, both experimental and clinical, and demonstrated very clearly that destruction of valves occurred despite recovery of venous patency. While it is possible that patency can be restored by early iliofemoral thrombectomy, the valve damage produced by the process and accentuated perhaps by the trauma of a Fogarty balloon catheter passed in a retrograde fashion leads to late venous insufficiency. This may be mild at first, but it is steadily and inexorably progressive as minimal valvular insufficiency leads to venous dilatation and finally gross incompetence.

The excellent studies of collateral venous circulation in the leg reported by Mavor and Galloway [7] also clarify the reasons for the conflicting results reported following thrombectomy. They point out that when the main femoral venous channel is occluded, the venae comitantes dilate and may be mistaken for a recanalized superficial femoral vein. With time the number of collateral channels decreases and those that remain become less tortuous. In these cases, the valves of the venae comitantes may remain competent even though the vessels are dilated, and a good clinical result is achieved. This observation leads to the hypothesis that multiple ligation of the incompetent valveless superficial femoral vein to provide a series of dams and decrease the back pressure may be beneficial in an advanced case of stasis disease following massive iliofemoral thrombosis. We have, in fact, performed this as an experimental procedure in one young man who was referred with severe intractable ulceration and edema that had resisted vein stripping, repeated skin grafting, perforator ligation and sympathectomy. When he stood up, the circumference of his foot increased 3 cm. in 2 minutes. The superficial femoral vein was ligated in only two

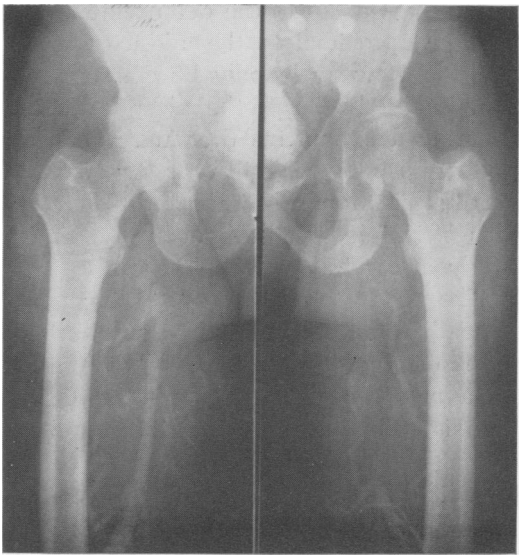

FIG. 5. Case 4. Iliofemoral thrombectomy performed on right leg 5 years ago, and left iliofemoral thrombosis treated medically one month later. Note the dilated superficial femoral vein and absence of valves on the right (operated) side and thrombosed common femoral vein with collateral channels. On the left the superficial femoral vein is thrombosed, but the saphenous, common femoral and iliac veins are patent. Edema was present in both legs.

places, just distal to the deep femoral vein and just proximal to the adductor hiatus. His foot now swells only 1.5 cm. When he stands and he keeps the ulcer healed by wearing a supportive dressing. While the follow-up period is still only 6 months, he has been temporarily improved. Therefore, this principle is also worthy of further study in carefully selected cases.

The poor late results and the impressive immediate rates of morbidity and mortality of iliofemoral thrombectomy have led us to a more conservative approach. Operation is still undertaken for threatening or actual ischemia of the limb and is considered if the case is one of recent extension of saphenous phlebitis into the deep system. However, the leg is first immediately elevated to 30–45 degrees and 10,000–15,000 units of heparin are injected intravenously. Operation is scheduled for 3 to 4 hours later, and is performed if dramatic improvement in the leg has not occurred, that is, marked reduction of swelling, better skin color and temperature, and loss of pain and numbness. So far, only two cases have come to operation in the past 5 years under this regimen. Unfortunately, in these two patients the results were similar to those in the present series, that is, one was shown to have residual thrombus at repeat venogram, the other had a pulmonary embolus, and both had a local hematoma or wound infection and residual edema.

Long-term follow-up of our patients that have been treated with elevation and intravenous heparin alone is not yet available, but we believe the end result will be very similar to that in the operated cases reported in this series. Strong support for this supposition was found in the end result in eight of the patients in the present operated series who previously had deep thrombophlebitis in the opposite leg, which was treated by medical means only. *In these eight cases the clinical result and the venogram in the unoperated leg were indistinguishable from those in the leg that underwent iliofemoral thrombectomy* (Fig. 5).

Conclusions

Iliofemoral thrombectomy has been proposed for the treatment of massive venous thrombosis to reduce the immediate morbidity, preserve venous valve function, and prevent late stasis edema and ulceration. A five-year follow-up study of cases previously reported upon indicates that the operation probably does none of these things. Therefore, extreme caution should be exerted in advising operation for massive venous thrombosis until the response to 3 or 4 hours of marked elevation and intravenous heparin has been observed. Exceptions to this rule include ischemia despite conservative treatment and perhaps cases of extension of saphenous thrombophlebitis into the common femoral vein.

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