Continuing Medical Education

The BEST-CLI Trial

This study will impact modern limb preservation practices.

BY CLARA M. GOMEZ-SANCHEZ, MD, AND MICHAEL S. CONTE, MD

Goals and Objectives

1) Explain the rationale and design for the BEST-CLI RCT.

2) Summarize the top line clinical results from the BEST-CLI trial.

3) Summarize recent clinical practice guidelines and how they relate to the trial.

4) Discuss how the trial results should inform limb salvage practice.

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*Following this article, an answer sheet and full set of instructions are provided (pg. 94).—**Editor***

Introduction

Patients with tissue loss in the setting of chronic limb threatening ischemia (CLTI) represent one of the most challenging groups of patients to manage. Without revascularization, 20-30% will progress to major amputation within a year after initial diagnosis of CLTI, and one-year mortality may also be greater than 20%.[1] Patients with CLTI are heterogenous in their clinical presentations, but prevalent rates of cardiac disease, diabetes, smoking, and chronic kidney disease are consistently high and can complicate management strategies and expected healing trajectories.[2] It is essential for any podiatric practice that a standardized approach to timely evaluation of limb perfusion is developed, as a failure to recognize ischemia

Without revascularization, more than 20% of CLTI patients can be expected to progress to major amputation within a year.

Continued on page 88

BEST-CLI Trial (from page 87)

may delay appropriate care and increase the risk of limb loss. It is also important for podiatrists to be aware of the available strategies for limb revascularization along with their relative benefits and limitations to fully inform patients and to guide clinical decision-making.

There has long been controversy among vascular surgery providers as to the best approach to revascularization in this complex patient population. Open surgical techniques including femoral endarterectomy and lower extremity bypass surgery have an established track record in the management of CLTI. Endovascular technologies for peripheral arterial disease have surged forward rapidly over the past two decades and are offered to patients from a combination of vascular surgeons, interventional cardiologists, and interventional radiologists. In many places, these endovascular techniques have superseded open surgical revascularization by vascular surgeons, or patients may not be seen by providers who offer open surgical procedures at all. Modern endovascular techniques include drug-eluting balloons and stents, mechanical and laser atherectomy, and intravascular lithotripsy in addition to plain-balloon angioplasty, bare metal, and covered stents that have been available for some time.

There is extensive literature on endovascular techniques that has established overall safety and short-term efficacy of various devices and techniques, but there have been few direct comparisons between open and endovascular treatment strategies for CLTI. There is also growing controversy about the value of some endovascular interventions offered to patients, as provider reimbursement for certain types of endovascular procedures far exceeds reimbursement for open surgical procedures despite a paucity of data on the long-term outcomes of those techniques.[3] With limited level 1 evidence in the field, vascular approaches offered to CLTI patients have become increasingly varied and largely reflective of individual provider skill sets, biases, and clinical workflow. Sitting on the other end of this morass, podiatrists and wound care specialists may feel unable to discern what is best for their patients or the quality of vascular care available in their community.

There are relatively few randomized-controlled trials to help guide decision making for patients with CLTI.

Until two years ago, the only randomized trial data available to directly compare revascularization strategies in patients with CLTI was from the Bypass versus Angioplasty in Severe Ischemia of the Leg (BASIL) trial which enrolled patients in the late 1990s through early 2000s. This multi-institutional randomized controlled trial from the United Kingdom compared outcomes in patients offered open surgical bypass vs. plain-balloon angioplasty as a first intervention for severe limb ischemia. The initial analysis published in 2005 with two years of follow-up did not demonstrate any difference in amputation-free survival or overall survival between the groups, and open surgery was more expensive in the short term.[4] However, post-hoc analysis demonstrated that patients randomized to surgery who survived beyond two years had significantly better amputation-free and overall survival.[5] A particularly interesting finding in the later analysis was that patients who had a bypass done after a failed angioplasty did significantly worse than those who had a bypass as an initial approach, questioning the notion of the endovascular intervention as a "free shot".[6] Some critical limitations of this trial are that the definition of severe ischemia was not as specific as the modern definitions of CLTI (representing a more heterogenous group that may bias the results towards angioplasty), there were poorly defined clinical and anatomic definitions for equipoise between the techniques, and the randomization process did not take into account the availability of ideal bypass conduit (saphenous vein).[7] Proponents of the BASIL trial cautiously interpreted the long-term outcomes to favor surgical bypass in CLTI patients expected to live more than two years, but limitations of the trial design allowed for ongoing debate in providers inclined to prefer endovascular intervention over open surgical bypass. Additionally, the endovascular interventions in this trial did not include drug eluting devices and few patients had stents placed, which is in stark contrast to the current landscape of vascular surgery. The lingering question about the ideal approach for revascularization inspired the design of a contemporary randomized controlled clinical trial that could more directly guide best practice in the care of CLTI patients.

In the BASIL trial open bypass had better amputation-free and overall survival in patients who survived more than two years.

Summary of the BEST-CLI trial

The Best Endovascular versus Surgical Therapy in Patients with CLTI (BEST-CLI) trial was an NIH-sponsored, randomized-con-

Continued on page 89

BEST-CLI Trial (from page 88)

trolled multi-institutional clinical trial enrolling patients from 150 sites representing five different countries.[8] This massive undertaking sought to determine whether patients with CLTI had better outcomes with endovascular interventions versus open surgical bypass and only included patients who were considered appropriate candidates for both. Each center was defined by having a multi-disciplinary "CLI Team." The vascular providers participating in the study included cardiologists and radiologists who did not themselves offer surgical options; however, in order to participate, they had to be partnered with surgeons who could offer open surgical bypass. This inclusive design helps to reflect a real-world environment of the care available to these patients.

Vascular surgeons, cardiologists, and interventional radiologists were included in the BEST-CLI trial.

All patients in the trial had infrainguinal arterial disease and presented with either gangrene, non-healing ischemic ulcers, or rest pain along with clearly defined hemodynamic parameters indicating significant ischemia. Patients had to be deemed as acceptable candidates for either open bypass or endovascular intervention by two members of the investigative team. The trial was designed to be pragmatic, allowing all available endovascular and open surgical techniques to be employed by the investigators. New device technologies were incorporated into the trial when commercially available, based on review by a designated technology committee.

The trial was designed as two parallel cohorts based on the pre-operative availability of an adequate great saphenous vein (GSV) for bypass. During the enrollment process, patients who had adequate GSV for a bypass were placed into one cohort and then randomized to endovascular vs. open approach, and patients who did not have adequate GSV for bypass were placed into a second cohort and then randomized. This is an important feature of the trial, as it reflects established surgical knowledge that the availability of a GSV to use as a conduit may significantly impact the outcome of a bypass. Enrollment was also intentionally stratified by the presence of tissue loss (versus rest pain alone) and involvement of significant below-knee arte-

Continued on page 90

Patients had to have rest pain, gangrene, or ischemic ulcers to be included the BEST-CLI trial.

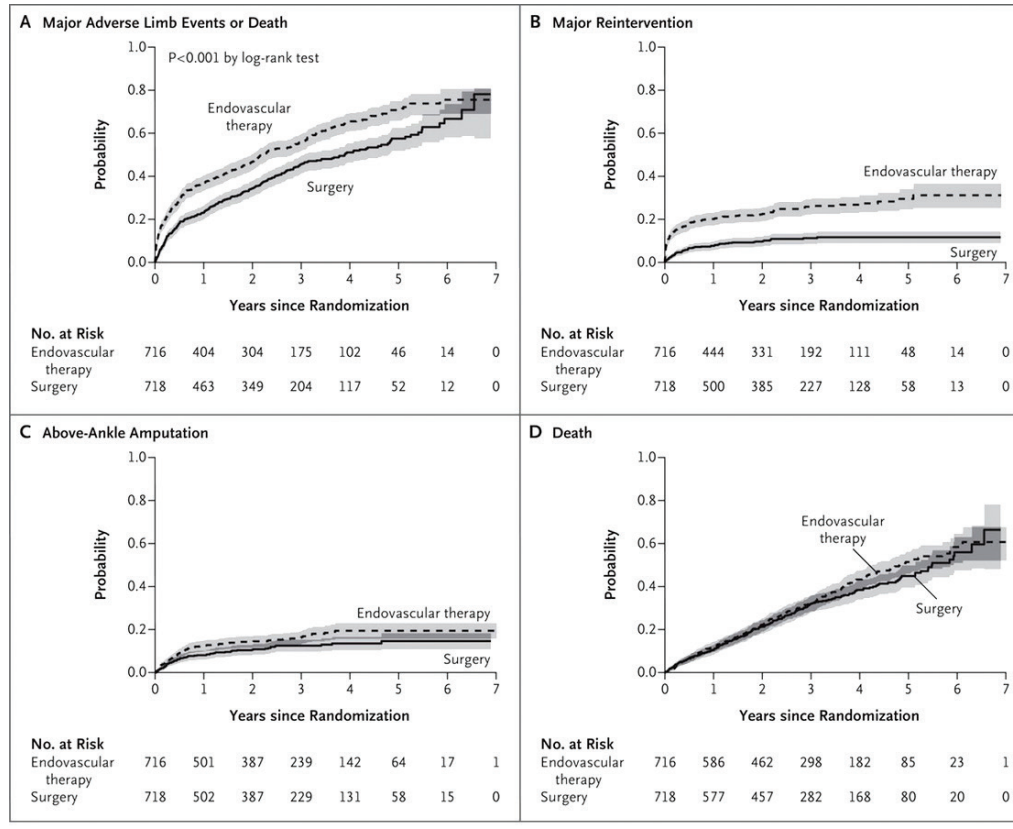

Figure 1: Kaplan–Meier Curves of the Primary Outcome and Its Components in Cohort 1. Shown is the primary outcome—a composite of major adverse limb events or death from any cause—among patients in the surgical group and the endovascular group in cohort 1 (patients who had a single segment of GSV) (Panel A). The components of the primary outcome were a major index-limb re-intervention, including a new bypass graft or graft revision, thrombectomy, or thrombolysis (Panel B); above-ankle amputation of the index limb (Panel C); and death from any cause (Panel D). Shading indicates the 95% confidence interval. Reprinted with permission from A Farber et al. N Engl J Med 2022; 387:2305-2316.

BEST-CLI Trial (from page 89)

rial disease to ensure balance between the treatment arms for these key factors. A total of 1830 patients were enrolled in the trial between 2014 and 2019.

The patients were followed for up to 84 months. The primary efficacy outcome defined by the study was a composite of major adverse limb events (above ankle amputation or major limb re-intervention such as a repeat bypass, thrombectomy, or thrombolysis) and death from any cause. The secondary outcomes collected included occurrence of a limb event at any time, post-operative death within 30 days, minor re-interventions, major cardiovascular events, and other serious adverse events.

In patients with adequate GSV, there were significantly fewer major adverse limb events in patients treated with surgical bypass.

There were 1434 patients with an adequate greater saphenous vein who were randomized in cohort 1, and they were followed for a median of 2.7 years. Technical success of the index procedure was 98% in the surgical bypass group and 85% in the endovascular group; 66 patients who had an early failure after endovascular intervention went on to receive a surgical bypass within 30 days. Significantly, more patients in the endovascular group had a major adverse limb event or death during follow-up compared to the open group (57.4% vs 42.6%, $p < 0.001$). This analysis was performed by intention-to-treat but there was a similar finding when the cohort was analyzed by treatment performed. There were significantly more major re-interventions in the endovascular group (23.5% vs. 9.2%) and more above-ankle amputations (14.9% vs. 10.4%). There were no differences in major cardiovascular events or perioperative deaths between the groups. Figure 1 (reproduced from the original *New England Journal of Medicine* publication) demonstrates the Kaplan-Meier curves of the primary outcome for cohort 1 (major adverse limb events or death as a composite) in panel A as well as the separate components of the primary outcome in panels B through D. The major drivers of the difference in the composite primary outcome are major re-interventions and above-ankle amputation, with no difference seen in the mortality over time between the randomized treatment arms. In other words, the improved outcomes in patients treated by open surgery were directly related to fewer repeat procedures, and improved limb salvage. Notably, these results in cohort 1 favoring open bypass were robust across nearly all subgroups analyzed.

There were 396 patients without an adequate greater saphenous vein who were randomized in cohort 2, and these patients had a median follow-up of 1.6 years. Technical success was 100% in the surgical bypass group and 80.6% in the endovascular group, with 26 patients who had early failure of endovascular therapy going on to a bypass within 30 days. There was no significant difference in major adverse limb events or death between the groups in this cohort in either the per-protocol or as-treated analyses performed. These data suggest that both treatment strategies were acceptably safe, although long-term mortality in this population remains notably high at approximately 10% per year.

In summary, BEST-CLI demonstrates that selected patients with CLTI who are acceptable surgical candidates and who have an adequate GSV for conduit may be better served with an initial open surgical

Continued on page 91

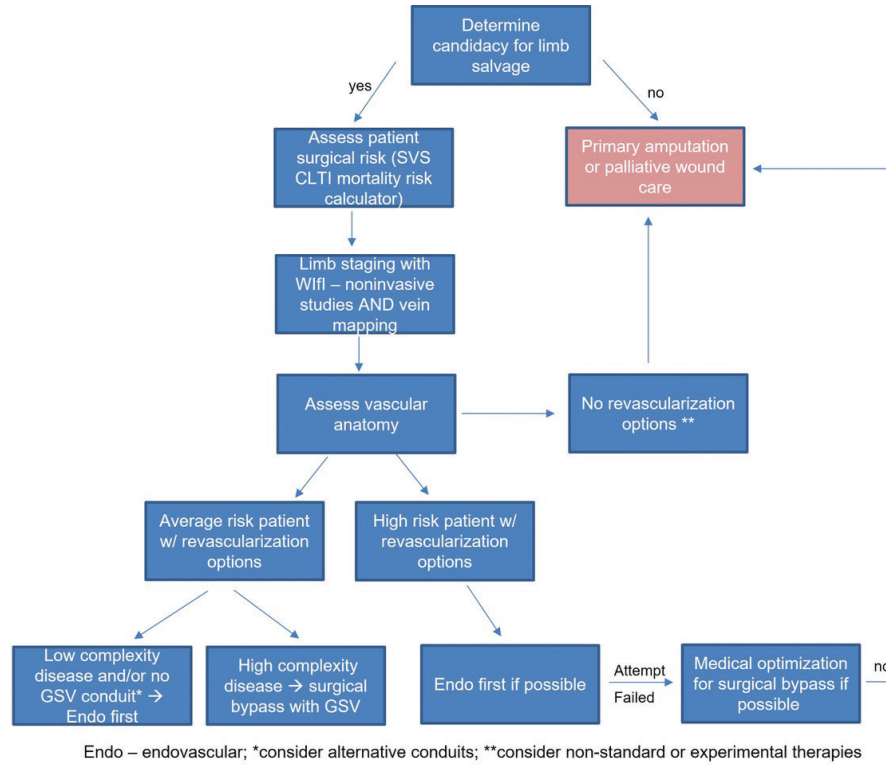

Figure 2: Suggested algorithm for revascularization for a patient presenting with CLTI.

BEST-CLI Trial (from page 90)

bypass. This advantage in limb salvage was not seen in patients who lacked an adequate GSV, but the power for cohort 2 was limited. With stricter definitions for ischemia in included patients, it is easier to identify how the BEST-CLI results relate to everyday practice. Additionally, once the patients were randomized within either cohort, the vascular providers could use their judgment as to the best techniques to employ, so the endovascular technologies used in BEST-CLI reflect modern options available to these patients, better than the earlier BASIL trial.

There are a few important limitations to be considered in this trial. Cohort 2 (no adequate saphenous vein) is relatively small and had shorter follow-up time; thus, it may be underpowered to identify a difference in limb salvage rates in this specific group. The decision to enroll the patient into the trial depended on the judgment of individual providers to determine whether there was clinical equipoise between endovascular and open surgery (essentially, the provider determined there was no good basis for a choice of one approach over the other) which introduces an element of selection bias into the inclusion process. Much additional data is expected to be published from the trial in the coming year, including a clearer description of the anatomic disease patterns treated, techniques employed, quality of life and cost-effectiveness results, and a range of secondary endpoints. It will also be of interest to examine the results by an as-treated analysis. Despite the limitations noted, BEST-CLI was well designed and carried out, and its seminal findings should influence practice guideline and current clinical management.

Calculating the WIfI stage can help identify patients who should have early referrals to vascular specialists.

Impacting Limb Salvage Practice

How should this landmark trial impact the practice of providers engaged in limb salvage? First, BEST-CLI reinforces the essential need for formal evaluations of perfusion status for patients with foot wounds and risk factors for ischemia in order to maximize chances for limb salvage. All patients with tissue loss in the foot should undergo a complete vascular examination, including non-invasive testing for those with absent pulses or risk factors for PAD. The Society for Vascular Surgery (SVS) has decision tools available online and via mobile app to classify the limb threat severity according to the WIfI staging system (Wound, Ischemia, and Foot Infection) which predicts amputation risk as well as the predicted benefit for revascularization.[9] Calculating the WIfI stage can help identify patients who should have early referrals to vascular specialists. In patients who are surgical candidates, ultrasound-based vein mapping to determine the presence of an adequate saphenous vein should be done to help guide decision-making on the best revascularization approach.

As with any randomized trial, there are important and still incompletely answered questions about generalizability of the BEST-CLI results. Recent data from the Vascular Quality Initiative suggest that of all patients who undergo any infra-inguinal revascularization for CLTI, more than 80% would be considered average surgical risk and thus acceptable candidates for open surgery.[10] Further data from the BEST-CLI trial is needed to clarify the spectrum of vascular disease complexity that was included in the trial populations, as well as the specific techniques employed and their outcomes.

Wound, ischemia, and foot infection are components of SVS Threatened Limb Classification System.

The Best-CLI results further emphasize the need for a multidisciplinary CLTI team with good working relationships and effective communication between podiatric and vascular providers. The vascular team should be capable of the full range of open and endovascular interventions to ensure that the revascularization approach is tailored to the patient's individual needs. The Global Vascular Guidelines published in 2019 state that the optimal revascularization strategy should be determined based on a combination of patient risk, limb threat severity (WIfI stage), the anatomic pattern of disease, and the availability of an adequate venous conduit.[9] The BEST-CLI results support this selective approach and demonstrate that an "endovascular-first" or more extreme "endovascular-only" approach to all patients with CLTI is likely a disservice to many. In circumstances where a vascular provider only offers endovascular procedures, it is important for them to build referral patterns with surgeons who perform bypass surgery. Patients should be informed of the trial's findings as part of shared decision-making. Podiatrists should be cognizant of these data as they relate to their current referral patterns and communications with patients.

Figure 2 demonstrates a suggested decision-making algorithm for patients with CLTI. Once a patient has been determined to be a candidate for limb salvage, multiple tools exist

Continued on page 92

BEST-CLI Trial (from page 91)

to determine the patient's operative risk category; one that found useful is the VQI CLTI mortality risk calculator.[10] Next, limb staging with WIfI should be pursued including hemodynamic vascular studies. Based on BEST-CLI trial results, we advocate for vein mapping simultaneously. At this point, a diagnostic angiogram should be performed to delineate the infrainguinal vascular anatomy; if this is done with knowledge of the presence of a vein conduit, then the vascular provider has all the information necessary to decide the optimal approach to revascularization.

Average risk patients with low complexity disease or those with higher complexity but no GSV available warrant a primary endovascular strategy. Those with higher complexity and GSV available should likely be offered surgical bypass as the initial therapy. For the group with complex disease and who lack adequate GSV, we consider using alternative conduits on a selective basis.

CLTI patients who are deemed as high surgical risk should be offered endovascular therapy as the definitive therapy; if this is not feasible anatomically or fails and there is a bypass target, multidisciplinary discussions are necessary to determine if a surgical approach should be undertaken. Some CLTI patients are best served by palliation or primary amputation. In the subset of patients with vascular anatomy that is not amenable to any standard revascularization options, various non-standard or experimental therapies may be considered, including deep venous arterialization and regenerative approaches.

Conclusion

In conclusion, BEST-CLI is a seminal trial in the fight to reduce limb amputations, and it is important for podiatric providers to understand the implications of its findings for care of patients with CLTI. Astute clinical judgment and experience is essential because no randomized controlled trial can include the full spectrum of patients in this heterogenous population; however, we now have high quality level 1 evidence to help support these treatment decisions about revascularization. It will be exciting to see further analysis on various subgroups and on the patient reported outcomes collected during the trial to further refine decision-making. **PM**

BEST-CLI is a seminal trial in the fight to reduce limb amputations, and it is important for podiatric providers to understand the implications of its findings for care of patients with CLTI.

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CME EXAMINATION

SEE ANSWER SHEET ON PAGE 95.

1) The Society of Vascular Surgery recommends that all patients with CLTI have their limbs staged with the SVS Threatened Limb Classification System to help guide management decisions. What are the components of this staging system?

A) Laterality, age of patient, wound.
B) Wound, ischemia, foot infection.
C) Infection, presence of diabetes, ambulatory status.
D) Wound, neuropathy, ambulatory status.

2) Why is it important to assess the vascular status of a patient presenting with a foot wound?

A) No podiatric procedure will succeed in patients with PAD.
B) Without revascularization, more than 20% of CLTI patients can be expected to progress to major amputation within a year.
C) To predict the likelihood of post-operative hematoma.
D) To increase reimbursement.

3) Vascular care in the United States is provided by which type of provider?

A) Cardiologists.
B) Interventional radiologists.
C) Vascular surgeons.
D) All of the above.

4) Which of the following is true about revascularization strategies in the modern era?

A) There are only limited options for endovascular therapies.
B) Choice of strategy is supported by numerous randomized-controlled trials.
C) There are relatively few randomized-controlled trials to help guide decision making for patients with CLTI.
D) Endovascular therapy is the superior strategy for most patients.

5) In the BASIL trial, which of the following was found in their post-hoc analysis?

A) Open bypass had better amputation-free and overall survival in patients who survived more than two years.
B) There was no difference between patients who underwent a bypass initially and those that underwent bypass after failed endovascular treatment.
C) Endovascular therapy was clearly superior.
D) Stents were clearly superior.

6) Which of the following is true about the providers involved in the BEST-CLI trial?

A) Only vascular surgeons were included.
B) Only cardiologists were included.
C) Vascular surgeons, cardiologists, and interventional radiologists were included.
D) Only providers who perform endovascular therapy could participate.

7) Which of the following is true about the patients included in BEST-CLI?

A) Patients with claudication were included.
B) No patients with infrapopliteal disease were included.
C) Patients without ischemia were included as controls.
D) Patients had to have rest pain, gangrene, or ischemic ulcers to be included.

8) Which of the following is true about the design of the BEST-CLI trial?

A) Patients with and without adequate GSV were separated into two cohorts.
B) Enrollment was stratified by presence of tissue loss vs. rest pain alone.
C) Patients had to be a candidate for both endovascular and open bypass.
D) All of the above.

Continued on page 94

(Continued from page 93)

9) In patients with adequate GSV,

A) Technical success was very low for the surgical bypass group.

B) There were significantly more heart attacks in the endovascular group.

C) There were significantly fewer major adverse limb events in patients treated with surgical bypass.

D) The mortality rate was higher for patients treated with surgical bypass.

10) Patients in cohort 2 who lacked adequate GSV

A) Had significantly better limb salvage rates with endovascular repair.

B) Had significantly better limb salvage rates with open bypass.

C) Had no difference in major adverse limb events or death between endovascular and open bypass.

D) Had a higher rate of mortality with endovascular repair.

SEE ANSWER SHEET ON PAGE 95.

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The BEST-CLI Trial
(Gomez-Sanchez and Conte)

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2.	A	B	C	D	7.	A	B	C	D
3.	A	B	C	D	8.	A	B	C	D
4.	A	B	C	D	9.	A	B	C	D
5.	A	B	C	D	10.	A	B	C	D

Medical Education Lesson Evaluation

Strongly agree [5]	Agree [4]	Neutral [3]	Disagree [2]	Strongly disagree [1]

1) This CME lesson was helpful to my practice ____

2) The educational objectives were accomplished ____

3) I will apply the knowledge I learned from this lesson ____

4) I will makes changes in my practice behavior based on this lesson ____

5) This lesson presented quality information with adequate current references ____

6) What overall grade would you assign this lesson?

A B C D

7) This activity was balanced and free of commercial bias.

Yes _____ No _____

8) What overall grade would you assign to the overall management of this activity?

A B C D

How long did it take you to complete this lesson?

_____hour _____minutes

What topics would you like to see in future CME lessons ? Please list :

_____

_____

_____

_____

_____