

LIPID OPTIMIZATION TOOL (LOT) DATABASE TO ACHIEVE LDL CONTROL IN A COMMUNITY CARDIOLOGY GROUP PRACTICE 2007 AUDIT

Authors: J. Niznick, C. Fulop, E. Sluzar Ottawa Cardiovascular Centre (OCC), Ottawa, Ontario, Canada

PURPOSE:

Lipid optimization to newer more aggressive targets has the potential to reduce cardiovascular events significantly and save tens of thousands of lives. Despite well-established benefits of lipid-lowering therapies, lipid targets are broadly underachieved. At the OCC we have developed a structured physician supervised, nurse managed lipid protocol and applied it via a flow chart based structured lipid management program. We have audited our practice over the last four years and developed a database capable of ongoing decision support and quality control measurement.

METHODS:

We have previously reported the use of the LOT to guide LDL control in patients at the OCC. For our 2006 practice audits, a database version of the LOT was developed and refined. This database is designed to risk stratify, to calculate LDL percent reduction to achieve to CCS, ATP III or user defined targets, to provide therapeutic decision support and to track sequential control rates to specified targets. Reports including risk factors, risk modifiers, coronary heard disease (CHD) equivalents and LDL control rates are generated automatically. For the 2007 audit parameters from 2780 sequential patients managed with the LOT by 13 OCC physicians were entered into the database.

RESULTS:

Of the 2780 patients audited in 2007, LDL control rates were 91% to an LDL of 3.0 mmol/L, 82% to an LDL of 2.5 mmol/L, 58% to an LDL of 2.0 mmol/L and 45% to an LDL of 1.8 mmol/L. 79% of patients were high or very high risk for cardiovascular events and 86% of these were on a statin. Control rates in statin treated patients were 94% to an LDL of 3.0 mmol/L, 87% to an LDL of 2.5 mmol/L, 63% to an LDL of 2.0 mmol/L and 48% to an LDL of 1.8 mmol/L. 87% to an LDL of 2.5 mmol/L, 63% to an LDL of 2.0 mmol/L and 48% to an LDL of 1.8 mmol/L. Eleven percent of patients were on combination therapy with statin + ezetimibe. Comparable Vascular Protection (VP)/Guideline Oriented Approach to Lipid Lowering (GOALL) registry control rates were 51%, 22% and 21 to LDL's of 2.5, 2.0 and 1.8 mmol/L respectively and Canadian Lipid Study-Observational (CALIPSO) control rates of 64%, 30% and 19% to LDL's of 2.5, 2.0 and 1.8 mmol/L respectively. Optimal target achievement rates are in the range of 79% to an LDL of 2.5 with statin monotherapy, 94% to an LDL target of 2.5 mmol/L with combination statin + ezetimibe therapy and 80% to an LDL target of 1.8 with combination statin + ezetimibe therapy based on EXPLORER study data.

CONCLUSION:

Although achieved LDL control rates at the OCC utilizing the LOT are among the best reported in the world literature, there is room for further improvement and increased use of combination therapy might result in even better control rates. Further testing of this hypothesis in real time clinical practice using the LOT database and protocol prospectively is warranted.
 Image: contract the contrac







Target LDL Control Rates High and Very High Risk Patients All pts. at targ on Stati % at targ 95 < 3.0 92 < 2.5 84 89 51 64 < 2.0 62 66 22 30 < 1.8 47 52 21 19



| $ \begin{array}{cccccccccccccccccccccccccccccccccccc$ | 0 C C 20 04 | 0 C C 20 05 | | | 0 C ST 20 07 | NEPTUNE ACTFAST CALIPSO ACTFAST OCC 2004 OCC 2005 OCC 2006 OCC 2006 OCC 06 ST OCC 07 ST | S |
|---|-------------------------|-------------------------|-------|---|--------------------------|--|---|
| 0 | U4 L | Inpub ata * | lishe | d | 07 | 000075 | |

 RT Yan et al. Guideline Oriented Approach in Lipid Lowering (GOALL)Rregistry data presented at CCC Symposium Oct 2005.
 MH Davidson et al. Results of the National Cholesterol Education (NCEP) Program Evaluation Project Utilizing Novel e-Technology (NEPTUNE) Il Survey and Implications for Treatment Under the Recent NCEP Writing Group Recommendations. Am J Cardiol 2005 Aug 15;96(4):556-63.

3) A Langer et al. Targeted Dosing of Atorvastatin Achieves Cholesterol Targets Quickly in Subjects with Diabetes or the Metabolic Syndrome (The ACTFAST Studies). Can J Cardiol 2005; Vol 21 Suppl C: Abstract 826, 253C.

4) C Bourgault et al. Stain Therapy in Canadian Patients with Hypercholesterolemia: The Canadian Lipid Study – Observational (CALIPSO). Can J Cardiol 2005; 21(13):1187-1193.

5) Yan et al. Contemporary Management of Dyslipidemia in High Risk Patients: Targets Still Not Met. Am J Med 2006; 119: 676-683.

Ottawa Cardiovascular Centre



Lipid Optimization Tool



Lipid Optimization Tool

Patient:

Pharmacy:

Responsible for Lipid Management:m Family Physician m Cardiologist m Endocrinologist

LIPID FLOW SHEET' - Use the following Table to Guide Intervention: NB*: UPPER STRATUM Exceeds CCS Recommendations for the Dx & Tx of Dyslipidemia and Prevention CVD 2006 / NCEP ATP III Guidelines 2004

| Risk Level | 10 year CHD Risk | No. Of Risk | 1° | arget: 2° | s 3° | Initiation of Lipid Lowering Therapy | |
|--------------------------------------|--|---|---------|--------------|---------|---|-------------------------|
| Count risk facto calculate 10-yea | rs or use Framingham tabl ar risk of hard CHD/CVD en | n tables/European SCORECARD to L /D endpoints. | | | | TG* < | |
| * CAD, PCI, CA | BG, TIA/CVA, PVD/bruits, | DM ² , CKD ³ | | 1.8 | < 3 | 1.5 | Immediately |
| High | > 20% | 3 | Rx to < | 2.0 | < 4 | 1.7 | Immediately |
| Moderate | 10-20% | 2 | Rx if ≥ | 3.5 | < 5 | 2 | Diet/Lifestyle 3 months |
| Low | < 10% | ≤1 | Rx if ≥ | 5.0 | < 6 | 2 | Diet/Lifestyle 6 months |

1) Count Risk Factors:

O Age M > 45 F > 55 O Family Hx CAD O Smoking O HPT O DM O LVH O HDL < 0.9 mmol/l 2) Identify Metabolic Syndrome (> 3 parameters):

O Abdominal obesity (Waist circumference: Male >102 cm (40 in.) / Female > 88 cm (34.6 in.) O TG > 1.7 mmol/L O HDL < 1 mmol/L (male)/< 1. 3 mmol/L (female) O BP > 130/85 O FBG 6.2-7 mmol/L

3) Identify secondary causes: O Diabetes O Hypothyroidism O Renal disease O Liver disease O Drugs & Alcohol



1 Monitor lipid profile, ALT and CK at baseline, 2 months then every 6 to 12 months 2 Diabetes carries the same CV risk as manifest CAD. DM+CAD impart much higher risk for subsequent CV events.

3 Chronic Kidney Disease



Secondary Prevention: % LDL (mmol/L) change to reach LDL target by risk category.

| ATP III Very High Risk | | CCS High Risk | | | | N | loderate | Risk | |
|------------------------|--------|---------------|---------|--------|------------|---|----------|--------|---------|
| Initial | Target | % Change | Initial | Target | % Change | | Initial | Target | % Chan |
| LDL | LDL < | LDL | LDL | LDL < | Min. 1 50% | | LDL | LDL < | Min. 14 |
| 5.00 | 1.8 | -64% | 5.0 | 2.0 | -60% | | 5.00 | 3.0 | -40% |
| 4.80 | 1.8 | -63% | 4.8 | 2.0 | -58% | | 4.80 | 2.9 | -40% |
| 4.60 | 1.8 | -61% | 4.6 | 2.0 | -57% | | 4.60 | 2.8 | -40% |
| 4.40 | 1.8 | -59% | 4.4 | 2.0 | -55% | | 4.40 | 2.6 | -40% |
| 4.20 | 1.8 | -57% | 4.2 | 2.0 | -52% | | 4.20 | 2.5 | -40% |
| 4.00 | 1.8 | -55% | 4.0 | 2.0 | -50% | | 4.00 | 2.4 | -40% |
| 3.80 | 1.8 | -53% | 3.8 | 1.9 | -50% | | 3.80 | 2.3 | -40% |
| 3.60 | 1.8 | -50% | 3.6 | 1.8 | -50% | | 3.60 | 2.2 | -40% |
| 3.40 | 1.8 | -47% | 3.4 | 1.7 | -50% | | 3.40 | 2.0 | -40% |
| 3.20 | 1.8 | -44% | 3.2 | 1.6 | -50% | | 3.20 | 1.9 | -40% |
| 3.00 | 1.8 | -40% | 3.0 | 1.5 | -50% | | 3.00 | 1.8 | -40% |

Dose response to Medication (statins & fibrates) % LDL Reduction

| Drug mg. | 5 | 10 | 20 | 40 | 80 | 200 | 400 | 900 |
|--------------|---------------|------------------|-----------------------|------------------|------------------|-----------------------|---------------|-----------------|
| Lovastatin | | | 24-28% | 28-34% | 39-42% | | | |
| Pravastatin | | 18 - 25% | 21-28% | 27-33% | | | | |
| Simvastatin | 23-30% | 27-32% | 30-40% | 36-43% | 45-47% | | | |
| Fluvastatin | 13% | 13% | 19% | 29% | 36% | | | |
| Atorvastatin | | 38-41% | 44-46% | 50 - 51% | 54 - 61% | | | |
| Rosuvastatin | 42-46% | 52% | 55% | 63% | | | | |
| Gemfibrozil | † Avoid in pa | tients with rena | a l impairment | | | | | 12 - 16% |
| Fenofibrate | † Avoid in pa | tients with rena | al impairment | | | 21-32% | | |
| Bezafibrate | † Avoid in pa | tients with rena | al impairment | | | | 2-15% | |
| Ezetimibe | | 19% | (Co-admini | stration with st | atin yields incr | ementa l 21% L | DL reduction) | |

Protocol: Initiate lipid lowering immediately in high-risk patients (concomitant with dietary/therapeutic lifestyle modification). 1) Target initial medication dose to ULDL by 40% for Moderate Risk or ULDL by 50% to minimum < 2.0 mmol/L for High Risk, Consider target LDL < 1.8 mmol/L for ATP III Very High Risk patients. Initiate therapy with dose required to achieve target LDL. NB: Initiate rosuvastatin at 10-20 mg (5 mg in Asians/CKD). *40 mg. contraindicted in Asian population.

- NB: Caution with simvastatin 80 mg. A to Z Trial and max dose statin in populations at risk for myositis.
- Ifinitial LDL at target, raise HDL and lower triglycerides to target values with appropriate intervention: diet, exercise, weight loss, refined carbohydrate restriction, moderate alcohol intake or medication: fibrate, Niaspan® or salmon oil/omega-3 supplements (1am OD-TID).
- If LDL and triglycerides high and HDL-C low, consider combination therapy (fibrate or Niaspan[®]). 4) If unable to raise HDL sufficiently, lower LDL to achieve TC/HDL< 4 and/or LDL/HDL< 3.
- Ifi nitial lipid profile normal look at other risk factors (LPa, homocysteine, apo-B and hs-CRP).
 Follow Total cholesterol, LDL, HDL, triglycerides, CK and ALT in 2 months then every 6 months.
- 7) If LDL not at target increase statin dose to achieve target or switch to more potent statin. If LDL target not achievable on monotherapy add cholesterol absorption inhibitor (ezetimibe) or bile acid sequestrant (cholestyramine or colesevelam). Doubling statin dose adds ~ 6 % LDL reduction. See Statin Cost Efficacy Grid. 8) Feedback results to patent to improve compliance.

Page 2

www.cvtoolbox.com

Lipid Optimization Tool

© Continuing Medical Implementation® Inc. November 2006



Statin Cost Efficacy

The Statin Cost Efficacy Grid details the cost and LDL lowering efficacy of all currently available statins. Statins and doses are highlighted based on evidence or cost efficacy. The green column highlights the minimum therapeutic bar for treatment of low and moderate risk patients. The orange column highlights the minimum therapeutic bar to halt atherosclerotic progression. The pink column highlights the minimum therapeutic bar for treatment of high risk patients or patients with atherosclerotic risk equivalents. The bright orange column highlights the minimum therapeutic bar to induce atherosclerotic regression. See the Lipid Optimization Tool for the therapeutic protocol.

| STATIN | Dose | Cost/tab\$ | %LDL Red | %LDL Red | %LDL Red Stellar ^[8] | %LDL Reduction | | | | | | |
|--|--|---|--|--|--|----------------|---------|-------|----------------|-------------------|----------|------|
| | | | | Law [7] | | 30% | 35% | 40% | 45% | 50% | 55% | 60 |
| Lovastatin | 20mg | 1.30 | 26 | 29 | | | | | | | | |
| (generic) | 40mg | 2.40 | 31 | 37 | | 2.40 | | | | | | |
| Pravastatin | 10mg | 1.05 | 22 | 20 | 20 | | | | | | | |
| (generic) | 20mg | 1.25 | 24 | 24 | 24 | | | | | | | |
| | 40mg | 1.50 | 30 | 29 | 30 | 1.50 | | | | | | |
| Simvastatin | 5mg | 0.45 | 27 | 23 | | | | | | | | |
| (generic) | 10mg | 0.89 | 30 | 27 | 28 | 0.89 | | | | | | |
| | 20mg | 1.10 | 35 | 32 | 35 | | 1.10 | | | | | |
| | 40mg | 1.10 | 40 | 37 | 39 | | | 1.10 | | | | |
| | 80mg | 1.10 | 46 [2] | 42 | 46 | | | | 1.10 | | | |
| Fluvastatin | 20mg | 0.75 | 19 | 21 | | | | | | | | |
| (generic) | 40mg | 1.05 | 29 | 27 | | 1.05 | | | | | | |
| | XL 80mg | 1.30 | 36 | 33 | | | 1.30 | | | | | |
| Atorvastatin | 10mg | 1.66 | 40 [3] | 37 | 37 | | | 1.66 | | | | |
| | 20mg | 2.08 | 45 | 43 | 43 | | | | 2.08 | | | |
| | 40mg | 2.24 | 51 | 49 | 48 | | | | | 2.24 | | |
| | 80mg | 2.24 | 58 [4] | 55 | 51 | | | | | | 2.24 | |
| Rosuvastatin | 5mg | 1.29 | 42 [5] | 38 | | | | 1,29 | | | | |
| | 10mg | 1.36 | 52 | 43 | 46 | | | | 1.36 | | | |
| | 20mg | 1.70 | 55 | 48 | 52 | | | | | 1.70 | | |
| | 40mg | 1.99 | 63 [6] | 53 | 55 | | | | | | 1.99 | |
| Average % n Cost based o | eduction: I on Ontario atin ba : | Jse to estimate ODB pricing-u sed on effi | e initial statin do pdated Februar i cacy, safet | se. Actual resp y 2007. For cos t y, evidenc | onse varies by p st to patient, add e and cost. | | | | and gend Re | der). vised Fe | bruary 2 | 2007 |
| EVIDENCE | | | | | | | | | | | | |
| | CARDO | | EVEDOAL | | PROVE IT (TH | | 1840710 | DARCI | ACT | POID | | |
| EVIDENCE COST HPS/ASCOT Ann Intern Med. 199 Am J Card 1998;81: Artericader Thromb Am J Card 1998;81: | C/CARDS 6;125:990-100 811-316. Vasc Biol. 199 582-587. | R 0. 5;15:678-682. | EVERSAL [5] Am J Card [6] EHJ 2002, [7] BMJ 328 5 [8] JACC 200 | lici 2003;91:33–41 4. (August) Abstract S 974040:1423. 3 (suppl(:315A-316A. / | PROVE-IT/TN iupplement: Abs 212, pa Abs 876-2. | T/IDEAL | /AtoZ/S | PARCL | ASTE | ROID | | |
| EVIDENCE COST HPS/ASCOT Am J Gard 1998;61: Am J Card 1998;61: Am J Card 1998;61: | /CARDS 6:125:990-100 311-316. Viace Bidl 199 582-587. fficacy | R 0. 5;15:678-682. | EVERSAL [5] Am J Carc [6] EHJ 2002, [7] BMJ 326 i [8] JACC 200 | lej 2000;91:33—11 4. (August) Abstract 5 774040:1423. 3 (suppl(:3154-316A. r | PROVE-IT/TN Supplement: Abs 212, pc Abs 876-2. | T/IDEAL | /AtoZ/S | PARCL | ASTE | ROID | | Pag |