

E-Selectin Expression Increased in Human Ruptured Cerebral Aneurysm Tissues - Pages 858-862

Wenqing Jia, Rong Wang, Jizong Zhao, Isabelle Yisha Liu, Dong Zhang, Xuejiang Wang, Xiaodi Han

Figure: A) Hematoxylin and Eosin (H&E) staining showed aneurysm wall pathology changes (A1 200x and A2 400x) when compared with normal superficial temporal artery (STA) wall (B1 200x and B2 400x). Aneurysm walls were disorganized with epithelial cell proliferation and artery media infiltrated with hyperplastic fiber components, monocytes, and accrementation nutrient vessels similar to granulation tissue. B) Immunohistochemistry showed E-selectin protein (brown) can be found mainly in aneurysms (A1 200x, A2 400x) but less in normal control artery (STA) walls (B1 200x, B2 400x).

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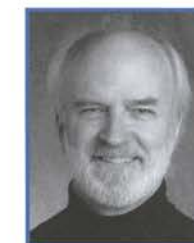
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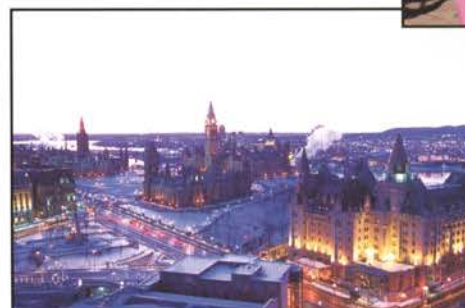
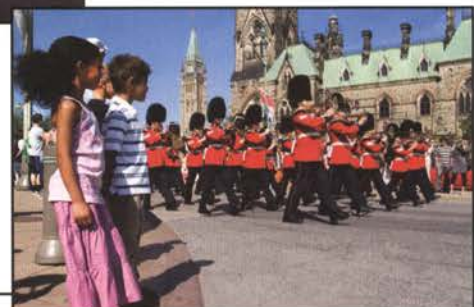
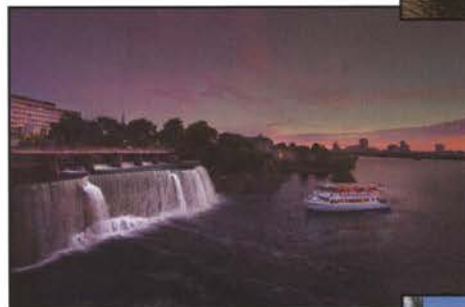
¹ Cymbalta® Product Monograph, Eli Lilly Canada Inc., April 8, 2011.



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See prescribing summary of pages A-13 to A-16



*Fictitious patient. May not be representative of all fibromyalgia cases.



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In fibromyalgia:

- In a 14 week study, LYRICA demonstrated significant pain reduction as early as week 1 ($p < 0.05$ for all doses). Mean changes in pain scores at the end of the study for LYRICA-treated patients were significantly greater versus placebo (300 mg/day, $n=183$: -1.75, $p=0.0009$; 450 mg/day, $n=190$: -2.03, $p < 0.0001$; 600 mg/day, $n=188$: -2.05, $p < 0.0001$; placebo, $n=184$: -1.04)³
- In another study of 26 weeks' duration of patients who initially responded to LYRICA during a 6-week, open-label phase, 68% of those who continued on their optimized dose ($n=279$) maintained a treatment response versus 39% of those on placebo ($n=287$). The time to loss of therapeutic response was longer in the LYRICA group ($p < 0.0001$)⁴

Also in neuropathic pain (NeP):

- Sustained pain relief (starting at week 2 for LYRICA 150-600 mg/day, $n=141$; $p < 0.05$ vs placebo, $n=65$) was demonstrated throughout a 12 week study in patients with DPN or PHN⁵

Demonstrated effective in relieving pain-related sleep difficulties^{1,6}

In fibromyalgia:

- In a 13 week study, LYRICA reduced overall MOS-Sleep Scale scores significantly more at the end of the study vs. placebo (300 mg/day -19.1, $p=0.0174$; 450 mg/day: -20.41, $p=0.0026$; 600 mg/day: -19.49, $p=0.0101$; placebo: -14.29)⁶

Also in NeP:

- LYRICA reduced sleep disturbances across several studies in DPN and PHN, of 8-12 weeks duration¹

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LYRICA (pregabalin) is indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy (DPN), postherpetic neuralgia (PHN) and spinal cord injury in adults. LYRICA may be useful in the management of central neuropathic pain in adults. LYRICA is indicated for the management of pain associated with fibromyalgia in adults. The efficacy of LYRICA in the management of pain associated with fibromyalgia for up to 6 months was demonstrated in a placebo-controlled trial in patients who had initially responded to LYRICA during a 6-week open-label phase.

LYRICA is contraindicated in patients who are hypersensitive to pregabalin or to any ingredient in the formulation or component of the container.

The most commonly observed adverse events ($\geq 5\%$ and twice the rate as that seen with placebo) in the recommended dose range of 150 mg/day to 600 mg/day in PHN and DPN patients were: dizziness (9.0-37.0%), somnolence (6.1-24.7%), peripheral edema (6.1-16.2%), and dry mouth (1.9-14.9%) and were dose related; in spinal cord injury patients: somnolence (41.4%), dizziness (24.3%), asthenia (15.7%), dry mouth (15.7%), edema (12.9%), constipation (12.9%), amnesia (10.0%), myasthenia (8.6%), amblyopia (8.6%), and thinking abnormal (8.6%); in fibromyalgia patients: dizziness (37.5%), somnolence (18.6%), weight gain (10.6%), dry mouth (7.9%), blurred vision (6.7%), and peripheral edema (6.1%). In LYRICA-treated fibromyalgia patients, the most commonly observed dose-related adverse events were: dizziness (22.7-46.5%), somnolence (12.9-20.7%), weight gain (7.6-13.7%), peripheral edema (5.3-10.8%). The most commonly observed adverse events in the PHN, DPN, spinal cord injury and fibromyalgia patients were usually mild to moderate in intensity. Discontinuation rates due to adverse events for LYRICA and placebo, respectively, were 9% and 4% in DPN, 14% and 7% in PHN, 21% and 13% in spinal cord injury, and 20% and 11% in fibromyalgia. There was a dose-dependent increase in rate of discontinuation due to adverse events in fibromyalgia.

There have been post-marketing reports of angioedema in patients, some without reported previous history/episodes, including life-threatening angioedema with respiratory compromise. Caution should be exercised in patients with previous history/episodes of angioedema and in patients who are taking other drugs associated with angioedema.

In clinical trials and in post-marketing experience, there have been reports of patients, with or without previous history, experiencing renal failure alone or in combination with other medications. Caution is advised when prescribing to the elderly or those with any degree of renal impairment.

There have been post-marketing reports of events related to reduced lower gastrointestinal tract function (e.g., intestinal obstruction, paralytic ileus, and constipation) in patients, some without reported previous history/episode(s), during initial/acute and chronic treatment with LYRICA, primarily in combination with other medications that have the potential to produce constipation. Some of these events were considered serious and required hospitalization. In a number of instances, patients were taking opioid analgesics including tramadol. Caution should be exercised when LYRICA and opioid analgesics are used in combination, and measures to prevent constipation may be considered, especially in female patients and elderly as they may be at increased risk of experiencing lower gastrointestinal-related events.

Dosage reduction is required in patients with renal impairment (creatinine clearance <60 mL/min) and in some elderly patients as LYRICA is primarily eliminated by renal excretion.

Please see Prescribing Information for complete Warnings and Precautions, Adverse Reactions, Dosage and Administration and patient selection criteria.

† Please consult Prescribing Information for complete Dosage and Administration instructions.



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