# Intradiscal methylene blue injection

In 2010, the results of a randomized controlled trial (RCT) were published concerning “intradiscal methylene blue injection” (IMBI), in which this intervention appeared to be very successful in relieving discogenic pain. Therefore, Geurts et al. decided to repeat this study to investigate whether they could replicate the published results. The results of the preliminary feasibility study gave reason to set up an RCT. The aim of this RCT is to evaluate if IMBI is a more effective treatment of discogenic low back pain as an intradiscal placebo intervention, and furthermore, to assess the cost-effectiveness of this intervention.

Consecutive discogenic low back pain patients referred to four specialized pain treatment facilities are being screened for eligibility. After a positive standardized provocation discography and informed consent, patients are randomized into two groups. The treatment group receives an intradiscal injection with methylene blue, lidocaine, and contrast, and the control group receives intradiscal isotonic saline with lidocaine and contrast. Main outcome measures are pain at the 6-month follow-up, patient's global impression of change, cost-effectiveness, quality of life, disability, and analgesic intake.

The importance of this study is emphasized by the fact that for intractable discogenic low back pain patients, evidence-based effective pain treatments are rare. If this study establishes clinical success and cost-effectiveness, IMBI could become the “pain treatment of choice” for a selected group of patients with chronic discogenic low back pain for whom noninvasive treatment options have failed [1)].

## Case series

### 2015

Fifteen consecutive patients with chronic lumbar discogenic pain enrolled in a multicenter prospective case series in two interventional pain treatment centers in the Netherlands. Six months after the intervention, 40% of the patients claimed at least 30% pain relief. In patients who responded, physical function improved and medication use diminished. We observed no procedural complications or adverse events. Predictors for success were Pfirrmann grading of 2 or less and higher quality of life mental component scores.

The findings of 40% positive respondents, and no complications, give reason to set up a randomized, double-blind, placebo-controlled, trial [2)].

### 2012

Twenty patients with discogenic low back pain (4 males, 16 females; mean age 45.6 years) refractory to conservative management were recruited. All subjects underwent MB injection in target lumbar intervertebral discs confirmed by provocative discography. The clinical outcome was assessed by visual analog scale (VAS) and Oswestry disability index (ODI) at baseline and 1, 3, 6 and 12 months after treatment. Successful outcome was described as minimum of 2 points reduction in pain intensity compared with the baseline.

VAS and ODI significantly decreased after one injection. The average VAS and ODI were reduced

significantly from 5.1 and 38.0 at baseline to 3.2 and 27.4 at 3 months after injection ($p<0.05$). However, the mean score of VAS at 12 month follow-up was 4.5 and we could not observe any difference between 12 months after injection and pretreatment. Eleven of twenty patients (55%) reported successful outcomes after intradiscal MB injection at 3 month follow up and the average VAS was reduced by 3.3±1.1 ($p<0.05$). At the time of 12 month follow up, pain had relapsed in 6 patients who have had satisfactory effect at 3 month follow up. Successful outcome was maintained in only 5 patients (20%) for 1 year.

The intradiscal MB injection is a short-term effective minimally invasive treatment indicated for discogenic back pain but it may lose its effectiveness long-term [3].

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8 patients treated with a one-time administration of methylene blue for discogenic back pain. Follow-up information was available between 2 months and over one year, depending on the patient.

Application of this treatment for these 8 patients for discogenic pain diagnosed by provocation discography showed only one clinical success at our center. Four patients had a time-limited clinical response in pain and/or function between 2 weeks and 5 months. Patient specific data are outlined in detail.

Low back pain ascribed to a discogenic source continues to be an elusive clinical entity to treat. Gupta et al. have reserved further treatment of methylene blue for discogenic pain until other controlled trials have been published [4].

### 2010

136 patients who were found potentially eligible after clinical examination and 72 became eligible after discography. All the patients had discogenic low back pain lasting longer than 6 months, with no comorbidity. Thirty-six were allocated to intradiscal MB injection and 36 to placebo treatment. The principal criteria to judge the effectiveness included alleviation of pain, assessed by a 101-point numerical rating scale (NRS-101), and improvement in disability, as assessed with the Oswestry Disability Index (ODI) for functional recovery. At the 24-month follow-up, both the groups differed substantially with respect to the primary outcomes. The patients in MB injection group showed a mean reduction in pain measured by NRS of 52.50, a mean reduction in Oswestry disability scores of 35.58, and satisfaction rates of 91.6%, compared with 0.70%, 1.68%, and 14.3%, respectively, in placebo treatment group ($p<0.001$, $p<0.001$, and $p<0.001$, respectively). No adverse effects or complications were found in the group of patients treated with intradiscal MB injection. The current clinical trial indicates that the injection of methylene blue into the painful disc is a safe, effective and minimally invasive method for the treatment of intractable and incapacitating discogenic low back pain [5] [6] [7].

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