



Should you take biologic agents (such as infliximab or etanercept) for ankylosing spondylitis? Facts and decision aid

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What is ankylosing spondylitis (AS)?

It is a type of arthritis which often affects the joints and ligaments of the spine. AS also affects the shoulders, hips, or other joints and can cause tendonitis. AS causes pain and stiffness and can limit movement in the back and other joints. Over time, the joints of the back may fuse, causing bent posture and making it harder to move around. The pain and damage limits people from being able to do daily routines at home and work. It may also affect a person's well-being.

The pain and stiffness can come and go, last for long periods, and be quite severe. If it is not treated, it may result in:

- problems doing daily routines
- bent posture
- fused joints
- need for surgery

What can you do on your own to manage your disease?

- Rest and relax
- Hot or cold packs
- Keep fit
- Motion that puts less stress on joints (such as swimming or walking)
- Visit a spa

What treatments are used for ankylosing spondylitis?

Four kinds of treatment may be used alone or combined. The common (generic) names of treatments are shown below.

Treatments to control pain and stiffness:

1. Pain medicines

- Acetaminophen

2. Non-steroidal anti-inflammatory drugs (NSAIDs), some of which are listed below

- Acetylsalicylic acid
- Indomethacin
- Piroxicam
- Celecoxib
- Meloxicam
- Rofecoxib
- Diclofenac
- Nabumetone
- Sulindac
- Ibuprofen
- Naproxen

Treatments to limit damage from the AS:

3. Disease modifying anti-rheumatic drugs (DMARDs)

- Methotrexate
- Pamidronate
- Sulphasalazine

4. Biologic agents

- Etanercept
- Infliximab

What about other treatments you may have heard about?

There is not enough research about the effects of some treatments. For example:

- Azathioprine
- D-penicillamine
- Thalidomide
- Prednisone

What are your choices? How can you decide?

Treatment for your disease will depend on your condition and your doctor's advice. You need to know the good points (pros) and the bad points (cons) about a treatment before you can decide.

When your doctor offers you a choice of infliximab because other drugs are not working well enough, this guide may help you.

Step 1: Be clear about the choice

What are the options?

Should you start taking biologic agents such as infliximab or etanercept when other treatments are not working well enough to control your ankylosing spondylitis?

When does this choice have to be made? Check one

- Within days Within weeks Within months

How far along are you with a choice? Check one

- You have not thought about it yet You are thinking about the choices
 You are close to making a choice You have made a choice

Step 2: Think about the pros and cons of the options

What does the research show?

Blocks of 100 faces show the 'best guess' for what happens to 100 people with ankylosing spondylitis if they try infliximab for 12 weeks.

No Treatment 	With Infliximab 
	
<p>9 people improve pain and stiffness a lot</p> <p>91 people may not improve a lot</p>	<p>53 people improve pain and stiffness a lot (<u>42 more people than with no treatment</u>)</p> <p>47 people may not improve a lot</p>
	
<p>60 have no side effects</p> <p>35 people may have common colds and lung infections</p> <p>5 people may have diarrhea</p> <p>0 no one may have tuberculosis</p>	<p>31 have no side effects</p> <p>51 people may have common colds and lung infections (<u>16 more than with no treatment</u>)</p> <p>15 people may have diarrhea (<u>10 more than with no treatment</u>)</p> <p>3 people may have tuberculosis (<u>3 more than with no treatment</u>)</p>

**** Ribbons show the strength of results from research studies.

-  **Platinum:** Research results from a well done review of 2 or more randomised controlled studies. Each study was well done and had at least 100 people in it.
-  **Gold:** Research results from at least one well done randomised controlled study that had at least 100 people in it.
-  **Silver:** Research results from studies that were not as strong. There may have been too few people in the study or the study was not well done.
-  **Bronze:** Expert views and experiences, or cases of what happened to someone taking a treatment.

What do you think of the pros and cons of biologic agents, such as infliximab?

The information below is from 3 studies of biologic agents. These studies lasted up to 10 months.

1. Review the common pros and cons.
2. Add any other pros and cons that matter to you.
3. Show how much each pro and con matters to you. Circle one (*) star if it matters a little to you and up to five (*****) stars if it matters a lot to you.

PROS AND CONS OF BIOLOGIC AGENTS SUCH AS INFLIXIMAB AND ETANERCEPT			
PROS	How much does it matter to you?	CONS	How much does it matter to you?
My pain and stiffness may improve a lot	* * * * *	Side effects: colds, headache, diarrhea, stomach pain	* * * * *
I am better able to do my daily routine	* * * * *	The drug may cause an instant allergy such as headache, nausea and hives	* * * * *
Takes only days/weeks to work instead of months	* * * * *	Major harms: tuberculosis (TB) and other serious infections Some of these infections have caused death.	* * * * *
Might decrease long-term damage to my spine	* * * * *	Unsure of what effect it will have if we still want to have children	* * * * *
Other pros:	* * * * *	Personal cost of medicine	* * * * *
		Unsure how easy it is to travel with this drug Need needles. Drug kept in the fridge.	* * * * *
		Other cons:	* * * * *

What do you think about taking biologic agents? Check one

You are willing to take this treatment
Pros matter more to you than the Cons

Unsure

You are not willing to take this treatment
Cons matter more to you than the Pros

Step 3: What role you want to have in choosing your treatment? Check one

You prefer to choose on your own after listening to the opinions of others.

You prefer to share the choice with: _____.

You prefer someone else to choose for you, namely: _____.



Step 4: Find out what else you need to help you make the choice

Facts	Do you know which options you have?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	Do you know both the good and bad points of each option?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Values	Are you clear about which good and bad points <i>matter most to you</i> ?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Support	Do you have enough support and advice from others to make a choice?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	Are you choosing without pressure from others?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Certainty	Do you feel sure about the best choice for you?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

If you answered "No" to many of these questions, you should talk to your doctor.

Step 5: Plan the next steps

What do you need to do before you make this choice?

For instance – talk to your doctor, read more about this treatment and other treatments.

Step 6: Share your answers on this form with your doctor

It will help your doctor understand what you think about this treatment.

Appendix A: Key Words are Defined

Ankylosing spondylitis (AS) is a type of arthritis which often affects the joints and ligaments of the spine. AS also affects the shoulders, hips, or other joints and can cause tendonitis. AS causes pain and stiffness and can limit movement in the back and affected joints. Over time, the joints of the spine may fuse together which may restrict movement and lead to bent posture. The pain and damage limits people from being able to do daily routines at home and work. It may also affect a person's well-being.

The pain and stiffness can come and go, last for long periods, and be quite severe. If it is not treated, it may result in:

- limited daily activities
- fused joints
- bent posture
- need for surgery

Pain varies from person to person. When it is severe, it can limit your daily routines at home and at work. Also, it can get in the way of how you feel about your well-being.

Tuberculosis or TB is a severe disease caused by a bacteria which attacks the lungs most of the time. People with TB disease often have a bad cough and fever. People may also have chest pain, feel tired, lose their appetite and lose weight, get chills or have night sweats. TB is spread through the air from person to person, when someone with infectious TB disease coughs or sneezes. Most people who are exposed to TB bacteria do not develop TB disease. In some cases, the person's immune system is able to kill the TB germs.



Appendix B: Facts and Numbers Behind the Decision Aid

These facts are only for those who want to know more about how the decision aid was made. To make your choice, you do not need to read it.

The following are the data sources, assumptions and calculations used in this decision aid. These are the best estimates based on available data. Data are subject to review as more information becomes available.

The information presented in this patient decision aid was based on evidence referenced in Appendix C (below).

It is assumed that patients who participated in the research studies used as the data sources for this patient decision aid would be similar to patients who would use the decision aid.

Author disclosure: None of the authors or their institutional affiliations can gain financially from the information contained within this patient decision aid.

Reading level: This decision aid is estimated to be able to be understood by patients with less than grade 8 reading level. Readability was calculated using the SMOG index.

This patient decision aid meets the following draft standards of the IPDAS Collaboration © 2004:

- Used a systematic development process
See credentials of review team. Physician & consumers revised the decision aid (see list of developers). The needs assessment and review is underway with patients and physicians who were not involved in its development.*
- Provided information on the condition, options, and their outcomes
health condition, options (including doing nothing), natural history, procedures involved, positive & negative features of options, probabilities of outcomes.
- Presented probabilities of outcomes (benefits and harms)
Uses event rates, comparing same denominator, same period of time and balanced frames. Describes uncertainty around probabilities (our best guess), using more than one method (numbers, words, diagrams). There is no tailoring of probabilities to individual risk categories. Refers to reference of source of probabilities.
- Clarified values and suggested ways to communicate values with the practitioner
Describes features and physical, emotional, and social effects (Summary and glossary). Asks people to think about which positive and negative features matter most using balance scales and rating exercises. Suggests patient share their worksheet with the practitioner
- Used personal stories of how others' made their decision
Not included.
- Guided or coached in deliberation and communication.
Uses step-by-step process. Uses worksheet and suggests sharing it with practitioner.
- No coaching offered but could be used with a coach.
- Disclosed conflicts of interest
Funding source disclosed for development and distributing. Discloses conflicts of interest of authors and affiliations.
- Delivered the decision aid on the internet. Currently available only as a PDF on the internet.
An interactive internet version is under development.*
- Balanced the presentation of options.
Compares positive and negative features with similar detail and emphasis (font, order, display). Field testing for balance is underway.*
- Used plain language.
Plain language specialist reviewed the decision aid and readability level < grade 8 by SMOG.
- Based information on up-to-date scientific evidence
pending_ Evaluated its effectiveness; currently being evaluated.*

* underway in CIHR grant 2004 (Brehaut, Tugwell & O'Connor)

Appendix C: References

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Van Den Bosch F, Kruijthof E, Baeten D, et al. Randomised double-blind comparison of chimeric monoclonal antibody to tumor necrosis factor alpha (infliximab) versus placebo in active spondylarthritis. *Arthritis Rheum*2002;46(3):755–65.