The links to patient experiences are strangely disembodied. They do not offer the patient's story as such. Rather they are snippets of people's experiences provided in response to predefined questions. For example, 'What will it be like having this operation or taking these drugs?'

Currently, the DIPEx web site does not capture the iterative process between people in self-help groups. This means that the site itself cannot provide the kind of 'mutual support and information sharing' in the rehabilitation process that self-help groups offer. However, DIPEx is innovative in its attempts to bring together professional concerns and consumer responses. This may be particularly useful to isolated consumers who do not have access to support groups. In addition DIPEx may prompt others to seek out actual rather than virtual support groups.

New drugs

Some of the views expressed in the following notes on newly approved products should be regarded as tentative, as there may have been little experience in Australia of their safety or efficacy. However, the Editorial Committee believes that comments made in good faith at an early stage may still be of value. As a result of fuller experience, initial comments may need to be modified. The Committee is prepared to do this. Before new drugs are prescribed, the Committee believes it is important that full information is obtained either from the manufacturer's approved product information, a drug information centre or some other appropriate source.

Bisoprolol fumarate

Bicor (Alphapharm)

1.25 mg, 2.5 mg, 5 mg and 10 mg tablets

Approved indication: heart failure

Australian Medicines Handbook Section 6.4.3

Some patients with heart failure will benefit from the addition of a beta blocker to their other treatments (see 'Beta blockers in heart failure' Aust Prescr 2000;23:120–3). Bisoprolol is one of the beta blockers which can be used in patients with stable, chronic, moderate to severe heart failure.

The drug is selective for beta-1 receptors. This selectivity is reduced at higher doses so the lowest effective dose should be used. Bisoprolol is lipophilic and hydrophilic. It has no intrinsic sympathomimetic activity.

First-pass metabolism reduces the bioavailability of bisoprolol to 80%. As half the dose is excreted unchanged in the urine and half is metabolised, lower doses should be used in patients with renal or hepatic impairment. The half-life of bisoprolol is normally 9–12 hours.

In the first Cardiac Insufficiency Bisoprolol Study (CIBIS) there was no significant difference in patient mortality between bisoprolol and placebo.[1] The second study (CIBIS II) enrolled more patients.[2] After an average of 1.3 years of treatment 228 (17%) of the 1320 patients given a placebo were dead compared with 156 (12%) of the 1327 patients given bisoprolol. A significant fall in sudden deaths suggests that the benefits of bisoprolol may be related to an antiarrhythmic action. Bisoprolol also resulted in significantly fewer admissions to hospital for deteriorating heart failure. The effects of bisoprolol were greatest in patients who had ischaemic heart disease and (New York Heart Association) class III heart failure.

It is important to begin with a low dose of bisoprolol and monitor patients closely as some patients' heart failure will get worse. The adverse reactions include bradycardia, hypotension and other effects typical of beta blockers.

In clinical trials, carvedilol and metoprolol have also reduced mortality when added to conventional treatment. There is no evidence to say which beta blocker is the most effective.

REFERENCES

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2. CIBIS-II investigators. The cardiac insufficiency bisoprolol study II (CIBIS II): a randomised trial. Lancet 1999;353:9-13.

Ertapenem

Invanz (Merck Sharp & Dohme)

vials containing 1 g as powder

Approved indication: specified infections

Australian Medicines Handbook Section 5.1.3

Ertapenem is one of the carbapenem antibiotics. These drugs have a broad spectrum of activity so are held in reserve for severe infections.

By inhibiting cell wall synthesis, ertapenem has a bactericidal action. *In vitro* it is active against anaerobes, Gram positive and Gram negative aerobic bacteria. Ertapenem is resistant to some beta-lactamases, but its *in vitro* activity against enterococci is limited and it is not effective against methicillin-resistant strains of staphylococci. Ertapenem is not active against *Pseudomonas aeruginosa.*

Although ertapenem can be used for infections caused by susceptible micro-organisms that are resistant to all other antibiotics, it has specific approval to be used empirically in acute pelvic infections and complicated intra-abdominal infections. It can be infused intravenously or injected intramuscularly. Infusions should take 30 minutes and should not be mixed with dextrose or other medications. Lignocaine 1% is used to reconstitute ertapenem for intramuscular injections.

Although the half-life of ertapenem is four hours, only one daily dose is needed. Most of the drug and its metabolites are excreted in the urine.

Ertapenem was compared with piperacillin/tazobactam in 665 patients with complicated intra-abdominal infections. There was a favourable clinical and microbiological response in more than 80% of the evaluable patients. Success rates exceeding 90% were seen, for both drugs, in the treatment of 412 women with acute pelvic infections. These infections included septic abortion and postpartum endomyometritis as well as post-surgical sepsis.

Serious infections can be life-threatening and cause symptoms which could be confused with adverse drug reactions. Approximately 20% of the patients given ertapenem had a drug-related adverse experience. Common adverse events include diarrhoea, headache, nausea and problems at the injection site. Seizures can occur and people with neurological disorders are particularly at risk. Abnormal laboratory results include altered liver function and neutropenia. There is a risk of anaphylaxis in patients who are hypersensitive to penicillin.

While there is now a choice of three carbapenems there currently seems little reason to switch to ertapenem apart from its once daily dose. Few clinical trials have been published and *in vitro* studies suggest its activity against some bacteria is less than that of imipenem and meropenem. This may limit its usefulness as an empirical treatment.

Editorial note

During the preparation of this new drug comment, some discrepancies emerged between the Australian product information and the prescribing information in the USA. There may be technical explanations for these differences, but the Editorial Executive Committee would like to draw readers' attention to some examples.

1. The adverse reactions section of the Australian product information does not include the American observation that there were more deaths (4.7% versus 2.6%) among the patients given ertapenem for complicated intra-abdominal infections.
2. The activity of ertapenem *in vitro* and in clinical infections varies between the documents. In the USA ertapenem has only been shown to be active against penicillin-susceptible strains of *Streptococcus pneumoniae* and beta-lactamase negative strains of *Haemophilus influenzae*. These caveats do not appear in the Australian product information.

Esomeprazole magnesium trihydrate

Nexium (AstraZeneca)

20 mg and 40 mg tablets

Approved indications: peptic ulcer, gastro-oesophageal reflux disease

Australian Medicines Handbook Section 12.1.4

Omeprazole is the most frequently prescribed proton pump inhibitor in a market worth nearly $250 million. Its patent recently expired, but the manufacturers have now marketed esomeprazole. This is the S-isomer of the omeprazole molecule.

Esomeprazole acts in the same way as omeprazole by inhibiting the proton pump in the parietal cells of the stomach (see 'Drugs that inhibit acid secretion' Aust Prescr 2000;23:57–9). In patients with gastro-oesophageal reflux disease esomeprazole 20 mg will keep the intragastric pH above pH4 for at least 16 hours in 24% of patients, compared with 14% of patients given omeprazole 20 mg.

In addition to the initial and maintenance treatment of patients with erosive oesophagitis, esomeprazole has also been approved for use in the treatment of peptic ulcers. It can be combined with amoxycillin and clarithromycin to eradicate *Helicobacter pylori* in patients with active or healed ulcers. A one week course of this combination is as effective, at healing duodenal ulcers associated with *H. pylori*, as a combination of omeprazole and antibiotics followed by a further three weeks of omeprazole. (Although a shorter course of treatment would be helpful, the trial did not study the outcome of giving omeprazole and antibiotics for just one week. As different regimens were compared it is difficult to draw conclusions about any difference between the drugs.)

The common adverse effects of esomeprazole include headache, diarrhoea, nausea and vomiting. Esomeprazole is metabolised by cytochrome P450 2C19 and 3A4 so there is a potential for interactions. Known interacting drugs include diazepam, cisapride, clarithromycin, citalopram, imipramine and phenytoin. Severe liver disease reduces the clearance of esomeprazole.

While esomeprazole has more effect on intragastric pH than omeprazole, this may not confer a significant clinical advantage. After eight weeks of treatment, a daily 20 mg dose of either drug will have healed more than 80% of patients with erosive oesophagitis. However, the manufacturers recommend using esomeprazole 40 mg for this indication. This higher dose will heal 68–78% of patients after four weeks and 87–90% after eight weeks.

Although esomeprazole has been approved for the symptomatic treatment of gastro-oesophageal reflux disease, it is not a first-line treatment for heartburn.[1]

REFERENCE

1. Smallwood R. The management of acid peptic disease. Aust Prescr 1995;18:97-9.

Fondaparinux sodium

Arixtra (Sanofi-Synthelabo)

2.5 mg/0.5 mL in pre-filled syringes

Approved indication: thromboembolic prophylaxis

Australian Medicines Handbook Section 7.1

Low molecular weight heparins, such as enoxaparin, can be used to prevent thromboembolism in surgical patients. They act by catalysing the inactivation of Factor Xa (see 'The new heparins' Aust Prescr 1996;19:104–8).

Fondaparinux is a pentasaccharide which also acts by potentiating the neutralisation of Factor Xa. This activity reaches a maximum three hours after a subcutaneous injection. There is no effect on platelet function, bleeding time or fibrinolysis.

Most of the dose stays in the circulation as it binds to antithrombin III. The half-life of fondaparinux is 17–20 hours. As the drug is mainly excreted unchanged in the urine it is contraindicated in patients with severe renal impairment. Clearance is also reduced in the elderly.

In a study of 1250 patients with a fractured femur, fondaparinux was compared with enoxaparin. The patients were treated once a day for at least five days, with most stopping their prophylaxis by the ninth day after surgery. At day 11, 8.3% of the patients given fondaparinux had evidence of a venous thromboembolism. This incidence was significantly less than in the enoxaparin group as 19% of those patients had thromboembolism.[1]

Another study involved 724 patients having elective knee surgery. The incidence of venous thromboembolism 11 days after surgery was 13% in patients treated with fondaparinux. Although the patients taking enoxaparin were given 30 mg twice daily, the incidence of thromboembolism was 28%.[2]

The comparative clinical trials used venography to show that fondaparinux had greater efficacy than enoxaparin. There were however no significant differences in the incidence of symptomatic thromboembolism or fatal pulmonary embolism.

As fondaparinux has an antithrombotic action, bleeding is its major serious adverse effect. In the clinical trials 2–3% of patients had a serious haemorrhage. Fondaparinux caused significantly more bleeding than enoxaparin after knee surgery.[2] Other adverse reactions reported in the trials of fondaparinux include anaemia, thrombocytopenia, altered liver function and injection site reactions. Particular caution is needed if fondaparinux is given to patients who have had spinal or epidural anaesthesia. There is a risk that a spinal or epidural haematoma may develop with the risk of long-term paralysis. Fondaparinux has no antidote.

REFERENCES

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2. Bauer KA, Eriksson BI, Lassen MR, Turpie AG. Fondaparinux compared with enoxaparin for the prevention of venous thromboembolism after elective major knee surgery. N Engl J Med 2001;345:1305-10.

Moroctocog alfa

Refacto (Wyeth)

vials containing 250 IU, 500 IU and 1000 IU

Approved indication: haemophilia A

Australian Medicines Handbook Section 7.4

Patients with haemophilia A are at risk of having severe bleeding after minor trauma because they lack factor VIII. To prevent this bleeding, patients can be given an infusion of concentrated factor VIII. These concentrates are plasma products, so there is always a risk of transmitting infection. This led to the development of recombinant factor VIII.

Moroctocog is a genetically engineered factor VIII produced using Chinese hamster ovary cells. The production process differs from that of previously marketed recombinant products (Kogenate, Recombinate) as human albumin is not included in the final preparation.

The indications for moroctocog are similar to those of the other recombinant factor VIII products. It can be used to prevent or control surgical bleeding. Moroctocog can be given to patients who have developed neutralising antibodies, but higher doses may be required. The incidence of these antibodies following treatment is similar to that seen after treatment with the other factor VIII products.

If necessary, the activity of moroctocog can be measured. It is important to know which assay is used as one method will underestimate the activity.

Parecoxib

Dynastat (Pharmacia Australia)

vials containing 20 mg and 40 mg powder for reconstitution

Approved indication: postoperative analgesia

Australian Medicines Handbook Section 15.1.1

Parecoxib is a non-steroidal anti-inflammatory drug. It is the prodrug of valdecoxib which reduces the production of inflammatory mediators by inhibiting the enzyme cyclo-oxygenase 2.

The plasma half-life of parecoxib is only 22 minutes because of its rapid conversion to valdecoxib. Analgesia begins within 15 minutes of an intravenous or intramuscular injection and reaches a peak in two hours. Valdecoxib is extensively metabolised and most of the metabolites are excreted in the urine. This metabolism includes cytochrome P450 3A4 and 2C9, so there is a potential for interaction with drugs which inhibit or induce these enzymes. Valdecoxib can also affect other liver enzymes. It may inhibit CYP2C19 and CYP2D6 creating the potential for more interactions.[1]

The analgesic effects of parecoxib have been studied in patients having dental, gynaecological or orthopaedic surgery. Parecoxib was more effective than placebo. Depending on the surgery, the duration of analgesia after a single dose was 6–12 hours. One study compared intramuscular and intravenous doses of parecoxib with placebo and intramuscular ketorolac in 304 patients having impacted wisdom teeth extracted. All the active treatments gave more pain relief than placebo and a 40 mg dose of parecoxib was significantly better than 20 mg. Ketorolac had a significant advantage over parecoxib in the first few hours after surgery, but parecoxib gave significantly more pain relief 16 and 24 hours after treatment.[2]

Parecoxib has only been approved for use as a single perioperative injection so most of the safety data refer to single doses. It can be difficult to separate the adverse reactions from

the effects of the surgery, but some adverse events occurred more frequently with parecoxib than with placebo. These include dyspepsia, changes in blood pressure, oliguria, oedema and itching. Caution is needed if the patient has hypertension or impaired cardiac, renal or hepatic function. Parecoxib can cause gastric erosions and ulcers so patients with a history of peptic ulcer may be at risk.

Non-steroidal anti-inflammatory drugs do have a role in postoperative analgesia.[3] For patients who cannot swallow, parecoxib is probably an alternative to ketorolac, but it has not yet been widely used.

REFERENCES

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Riluzole

Rilutek (Aventis Pharma)

50 mg tablets

Approved indication: amyotrophic lateral sclerosis

Australian Medicines Handbook Section 16.8

Amyotrophic lateral sclerosis is one of the motor neurone diseases. The degeneration of neurones progressively leads to bulbar palsy. Most patients die of respiratory failure or choking within three years of diagnosis.

The cause of the disease is unknown, but one theory is that there is an accumulation of glutamate in the affected neurones. One of the actions of riluzole is inhibiting the release of glutamate so it has been studied to see if it has neuroprotective effects.

In a placebo-controlled trial the deterioration in muscle strength was significantly slower in patients who had been treated with riluzole. After one year 57 of the 77 patients given riluzole were alive while only 45 of the 78 patients given placebo had survived.[1] This difference (74% versus 58%) was statistically significant.

A dose-ranging study established 100 mg daily as the best balance between benefit and harm.[2] Patients take 50 mg twice a day. The tablets are well absorbed, but their bioavailability is reduced by food. There is extensive hepatic metabolism, mainly involving cytochrome P450 1A2. This means there is a potential for interactions with drugs such as amitriptyline, quinolones and caffeine (CYP1A2 inhibitors), and rifampicin (CYP1A2 inducer). Most of the metabolites are excreted in the urine, so riluzole should be used with caution in patients with renal or hepatic impairment.

Patients need regular monitoring of their liver function particularly in the first few months of treatment. A fever should prompt a check of the white blood cell count as neutropenia has been reported. The most common adverse effects of riluzole are asthenia, nausea and decreased lung function. Approximately 14% of the patients in clinical trials withdrew because of adverse events.

Although riluzole offers hope to patients with amyotrophic lateral sclerosis, it is not a cure. In the dose-ranging study the unadjusted outcome did not show a significant benefit. After 18 months 134 of the 236 patients given 100 mg riluzole had survived without a tracheostomy but so had 122 of the 242 patients given a placebo.[2] In the double-blind trial, the reduction in mortality declined after the first year of therapy. Treatment appeared to be of most benefit to patients whose disease began with bulbar involvement. When the onset involved the limbs, riluzole had no significant survival advantage over placebo[1], however this finding was not confirmed in the second study.[2] Overall riluzole probably increases survival, without a tracheostomy, by two to four months.

REFERENCES

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2. Lacomblez L, Bensimon G, Leigh NP, Guillet P, Meininger V. Dose-ranging study of riluzole in amyotrophic lateral sclerosis. Lancet 1996;347:1425-31.

Sirolimus

Rapamune (Wyeth)

1 mg/mL oral solution in 60 mL glass bottles

Approved indication: renal transplantation

Australian Medicines Handbook Section 14.1.1

Patients require immunosuppression after renal transplantation to prevent rejection of the allograft. Although cyclosporin is often used as an immunosuppressant it is associated with nephrotoxicity and hypertension. Including sirolimus in the regimen may enable cyclosporin to be withdrawn 2–4 months after transplantation.

Sirolimus is a substance produced by *Streptomyces hygroscopicus*. It inhibits antibody production and the activation and proliferation of T lymphocytes. Treatment should begin as soon as possible after the transplant.

The oral solution is rapidly absorbed. As its bioavailability of 14% is affected by food, patients should consistently take the drug with or without food. Sirolimus is metabolised by CYP3A4, so it should not be taken with grapefruit juice. Other drugs which affect this enzyme may increase or decrease concentrations of sirolimus. Blood concentrations of sirolimus should be routinely monitored. As cyclosporin is one of the drugs which inhibit the metabolism of sirolimus, the dose of sirolimus required to maintain the required blood concentration will increase if cyclosporin is withdrawn from the treatment regimen. The long half-life of sirolimus (62 hours) needs to be considered when assessing the effect of a change in dose. Only 2% of the drug and its metabolites are excreted in the urine.

A study of 719 patients compared two doses of sirolimus with azathioprine, in addition to a regimen of cyclosporin and corticosteroids. After a year, the acute rejection rate in the azathioprine group was 31% compared with 22% in patients taking 2 mg sirolimus daily and 15% in those taking 5 mg sirolimus daily. The rejection episodes were less severe in the

sirolimus group, but after a year graft survival was similar in all groups.[1]

Treatment with sirolimus seemed to exacerbate cyclosporin-induced renal dysfunction and hypertension. The patients treated with sirolimus also had significantly higher creatinine concentrations. As this may be due to a drug interaction, regimens which discontinue cyclosporin could have an advantage.

In a clinical trial 430 patients were randomised to stop cyclosporin after three months or continue taking it with sirolimus and corticosteroids. Although graft survival after one year was similar (95–97%), the patients who had cyclosporin withdrawn had a significantly higher glomerular filtration rate. They also had significantly lower blood pressure. However, withdrawal of cyclosporin was associated with a higher incidence of acute rejection (20% versus 13.5%).[2]

Most patients will experience adverse events while taking a combination of drugs after renal transplantation. Very common adverse reactions include peripheral oedema, anaemia, thrombocytopenia, epistaxis and arthralgia. Immunosuppression increases the risk of infection and the development of malignancies. Patients are advised to protect themselves from sunlight to limit the risk of skin cancers. Prophylaxis against *Pneumocystis carinii* is also recommended. Sirolimus is associated with increases in cholesterol and lipids which may be severe enough to require drug treatment.

The best regimen for patients after a renal transplant is still to be determined. While sirolimus has some benefit its long-term safety and effectiveness are unknown. It also needs to be compared with other regimens, such as those using mycophenolate mofetil.

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2. Johnson RWG, Kreis H, Oberbauer R, Brattström C, Claesson K, Eris J. Sirolimus allows early cyclosporine withdrawal in renal transplantation resulting in improved renal function and lower blood pressure. Transplantation 2001;72:777-86.

NEW FORMULATIONS

Amino acid dipeptide 14.4%

Glamin (Baxter Health Care)

solution in 250 mL, 500 mL and 1000 mL glass bottles

Lenograstin (rch)

Granocyte (Amrad)

263 microgram (33.6 million IU) and 105 microgram (13.4 million IU) in single-use vials

Mesalasine

Salofalk (Orphan)

granules in 500 mg and 1 g sachets, and 2 g/60 mL and 4 g/60 mL enemas

Oxcarbazepine

Trileptal (Novartis)

60 mg/mL oral suspension

NEW COMBINATIONS

Dorzolamide/timolol

Cosopt (Merck Sharp & Dohme)

eyedrops containing 2.0% dorzolamide/0.5% timolol/mL

Ibuprofen/codeine phosphate

Nurofen Plus (Boots)

200 mg ibuprofen/12.8 mg codeine phosphate tablets

NEW STRENGTHS

Levonorgestrel

Postinor-2 (Schering)

750 mg tablets

Approved indication: emergency contraception

Australian Medicines Handbook Section 17.1.4

For many years health professionals have been cutting up packets of contraceptive pills to provide women with post-coital contraception. This use of the combined pill in the Yuzpe regimen has never been approved by the Therapeutic Goods Administration. An alternative to this regimen was a high dose of progestogen, but no suitable formulations were available.

This new strength of levonorgestrel has been approved for emergency contraception. One tablet should be taken within 72 hours of unprotected intercourse. This is followed by a second tablet 12 hours later. The sooner treatment begins the more effective it is.

A double-blind study compared this regimen with the Yuzpe regimen. There were 11 pregnancies in the 976 women who took levonorgestrel, and 31 in the 979 women who used the Yuzpe regimen. When the women's menstrual cycles and probability of conception were taken into account levonorgestrel prevented 86% of expected pregnancies and the Yuzpe regimen prevented 58%.[1]

Both regimens cause nausea and vomiting, however they occur significantly less frequently with levonorgestrel. If the woman vomits within two hours of taking levonorgestrel an additional tablet can be taken.

Women should not use this product as their regular form of contraception. A request for emergency contraception is an opportunity to discuss the woman's ongoing contraceptive needs. This should not be overlooked even if levonorgestrel becomes available, as it is in the UK, from pharmacies without a prescription.[2]

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Follitropin alfa

Gonal-F (Serono)

1200 IU powder for injection

Metformin hydrochloride

Diabex (Alphapharm)

1000 mg tablets

NEW PROPRIETARY BRANDS

Aciclovir

Zyclir (Arrow)

200 mg and 800 mg tablets

Cephalexin

Cefalexin-BC (Biochemie)

250 mg/5 mL powder for oral suspension

Flucloxacillin sodium

Floxsig (Sigma)

250 mg and 500 mg capsules

Midazolam

Midazolam Injection BP (Mayne Pharma)

5 mg/mL in 1 mL ampoules

Propofol

Propofol-BC (Biochemie)

200 mg/20 mL ampoules, 500 mg/50 mL and 1000 mg/100 mL vials

Pharmacokinetics Made Easy
Second edition, 2002

Donald J. Birkett. Pharmacokinetics Made Easy. 2nd ed.
Sydney: McGraw-Hill Australia; 2002. 132 pages.
Price $23.95. Available from McGraw-Hill (02) 9415 9888.

This book collects together all the articles which appeared in the *Australian Prescriber* series 'Pharmacokinetics made easy'. The first edition was successful and so it has been updated and a new chapter added. *Australian Prescriber* readers can get 15% discount by quoting code BIR0802.

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1. False	3. True	5. False
2. False	4. False	6. True

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